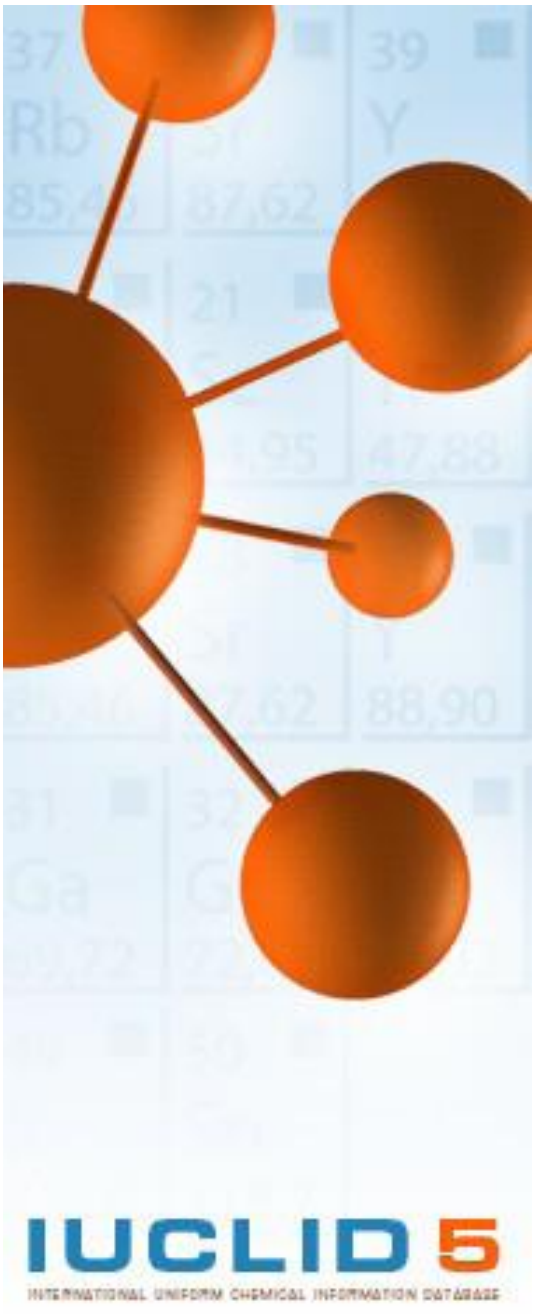

IUCLID 5

Guidance and Support

Report Generator

Summary of Product Characteristics (SPC)

User Manual

January 201
Version 1.1

IUCLID 5 is developed by the European Chemicals Agency in association with the OECD

PREFACE

The aim of this guidance document is to provide insight into what kind of information the Report Generator plug-in captures from IUCLID 5 documents to create a draft Summary of Product Characteristics (SPC). The principle rules underlying the automatic generation of a SPC rtf document are explained.

This guide also provides hints and tips on how to optimise data entry in the IUCLID 5 source records in such a way that any manual revision work is limited to a minimum.

ORGANISATION OF THIS GUIDANCE DOCUMENT

This document is organised into the following two main parts:

- Part I: Principles of SPC generation
  Describes the general rules and format underlying the generation of a SPC template using the Report Generator including examples and practical hints.

- Part II: Specifications of the SPC Template
  Provides the specifications of the SPC Template showing the IUCLID source fields and how they are inserted in the SPC, together with specific rules where appropriate. The general rules used are not re-iterated, but described in Part I.

RELATED DOCUMENT

The installation of the Report Generator is described in the **Report Generator Installation Guide** available on the IUCLID website: http://iuclid.eu.

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PART I: PRINCIPLES OF SPC GENERATION

1 GENERAL INTRODUCTION

1.1 SPC REQUIREMENTS UNDER BPR

The scope of the summary of the biocidal product characteristics (SPC) is defined by the article 22 of the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012). ECHA in cooperation with the European Commission, Member States Competent Authorities and Industry representatives developed a template that is used in the IUCLID Report Generator. All information that appears in the generated report has to be previously inserted into IUCLID, in a structured way.

The draft report should be readily understandable as a stand-alone document.

The draft report can be generated in rtf and xml format.

1.2 PURPOSE OF THE REPORT GENERATOR (IN THE SCOPE OF THE SPC)

The Report Generator has been designed to assist in preparing a draft SPC.

It generates the complete structure of the SPC report including all main sections and subsections.

The plug-in can generate a SPC document as rtf file (rich text format), which reflects the underlying data contained in the relevant IUCLID documents. Although possible, editing of the generated SPC using any text processing program, should be limited to cases where data cannot be edited upfront in the data source(s).

The SPC report can be generated several times, if some corrections are needed in the data source in IUCLID.

Hint:

It is good to start by generating a draft SPC based on a biocidal product dataset (instead of a biocidal product authorisation dossier), to see if all fields are filled-in correctly, and then insert all missing information in the relevant IUCLID fields. It is strongly recommended to update the IUCLID dataset instead of changing IUCLID data in the draft SPC. Be aware of the risk that any manual changes made to IUCLID 5-born information in the SPC may result in inconsistencies, if the IUCLID 5 records are not updated accordingly.

The capture of IUCLID 5 data is controlled by a number of rules used to extract and transfer the most relevant information. The user is responsible to verify the quality of the generated SPC.

2 HOW TO INSTALL AND RUN THE SPC PLUG-IN

A separate manual which gives guidance on how to install and run the plug-in (**Report Generator Installation Guide**) is available on the IUCLID website: http://iuclid.eu).

3 FORMAT AND GENERAL RULES UNDERLYING THE SPC GENERATION

In this section the general rules underlying the SPC generation are explained and exemplified. It is demonstrated how the Report Generator works in the scope of SPC generation and what kind of IUCLID 5 information is captured.

3.1 LAYOUT AND FORMAT OF THE GENERATED SPC

3.1.1 Structure

The Report Generator generates the complete structure of the SPC report including all main sections and subsections:

1. Administrative information
    - 1.1. Trade name of the product
    - 1.2. Authorisation holder
    - 1.3. Manufacturer(s) of the product
    - 1.4. Manufacturer(s) of the active substance(s)
2. Product composition and formulation
    - 2.1. Qualitative and quantitative information on the composition of the product
    - 2.2. Type of formulation
3. Authorises use(s)
4. Hazard and precautionary statements
    - 4.1. Classification and labelling of the product according to the Regulation (EC) 1272/2008
    - 4.2. Classification and labelling of the product according to the criteria in Directive 67/548/EEC (DSD) and Directive 1999/45/EC (DPD)
5. Directions for use
    - 5.1. Instructions for use
    - 5.2. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
    - 5.3. Instructions for safe disposal of the product and its packaging
    - 5.4. Conditions of storage and shelf-life of the product under normal conditions of storage
6. Other information

The information on Authorisation holder is not retriewed from IUCLID 5 and has to be inserted manually by the user, based on R4BP 3 data.

3.1.2 Document file format

The document can be created in XML DocBook format (Extensible Markup Language) or in rtf format (rich text format). The rtf format is used for cross-platform document interchange. Most word processors are able to read and write rtf documents.

After the title page of the SPC, a table of contents is generated; it includes the page numbers and hyperlinks that can be used to navigate to the bookmarked destinations.

Predefined styles are applied to headings (e.g. SPC Heading 1) and the Word field code for ToC (Table of contents) is inserted by the plug-in.

When a SPC is generated by the plug-in, only the heading *Table of contents* is printed and the following message: "Please press CTRL+a and afterwards F9 to update the index". As instructed, the index is created if you:

- press the key combination CTRL+A (press and hold down the CTRL key and the press the A key on the keyboard) to mark the entire document and then
- press the F9 key on the keyboard.

3.1.3 General rules on retrieving information from IUCLID

All general rules concerning information captured from IUCLID 5 are described in PART II of this document which contains the Specifications of the Summary of Product Characteristics template.

3.1.4 Handling information captured from text fields and rich text areas

In IUCLID 5, different text field types are provided. Information captured from these fields is handled as follows:

- Single-line text field: the content of these fields is transferred without any changes.
- Multi-line text field: the content of these fields is transferred as it is, including line breaks. Only in some cases the latter may be removed.
- Rich text (html) area: allows to specify fonts, colours, bullets, and other text attributes and to insert tables. The plug-in keeps most of the formatting, including tables.

Some of the IUCLID 5 fields do not allow rich text. In these cases, the user can edit the retrieved content manually.

4 GUIDANCE ON SPECIFIC SPC SECTIONS

In the following section, examples of IUCLID data and the outcome in the generated draft SPC are presented. All data appearing in the example SPC used in this document are used for exemplification purposes only. The data might be unrealistic.

Hint:

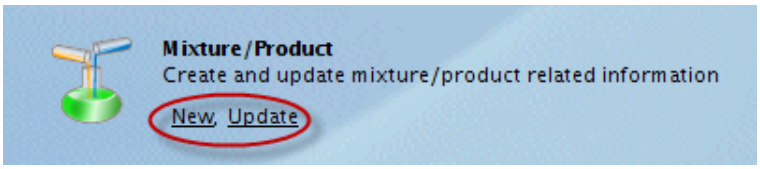
Please see refer to the ‘BPR dossier creation IUCLID Quick Guide’ on the IUCLID website before creating a biocidal product dataset, if you are not familiar with IUCLID. A video-tutorial is also available.

http://www.iuclid.eu/index.php?fuseaction=home.documentation#bprmanual

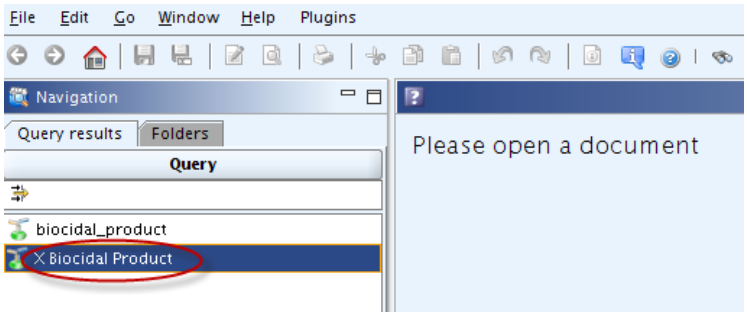
4.1 PRODUCT DATASET CREATION

To start inserting data in the biocidal product dataset follow the path shown on the screen shots below, starting from the home page of IUCLID 5.5.

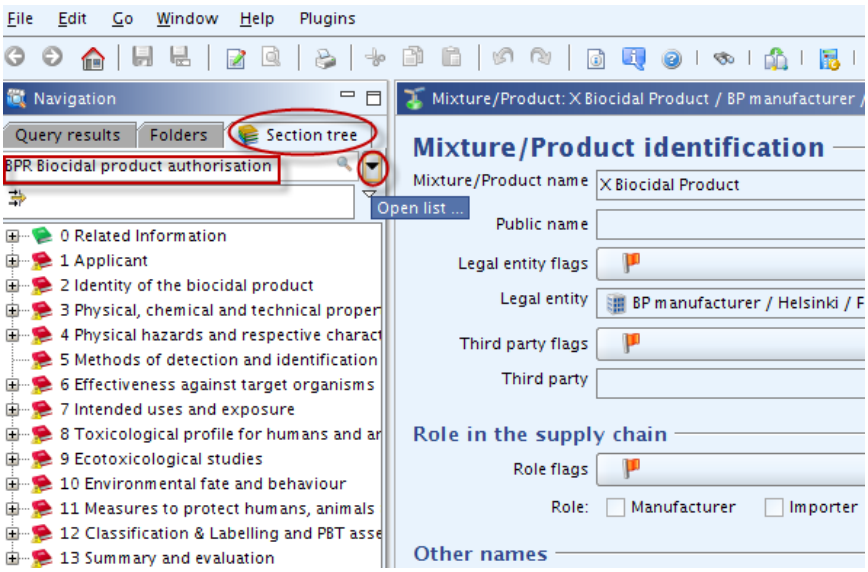
If you need to create a new biocidal product, select New. If you have already created a biocidal product for which you aim to generate a draft SPC, select Update to retrieve your dataset.



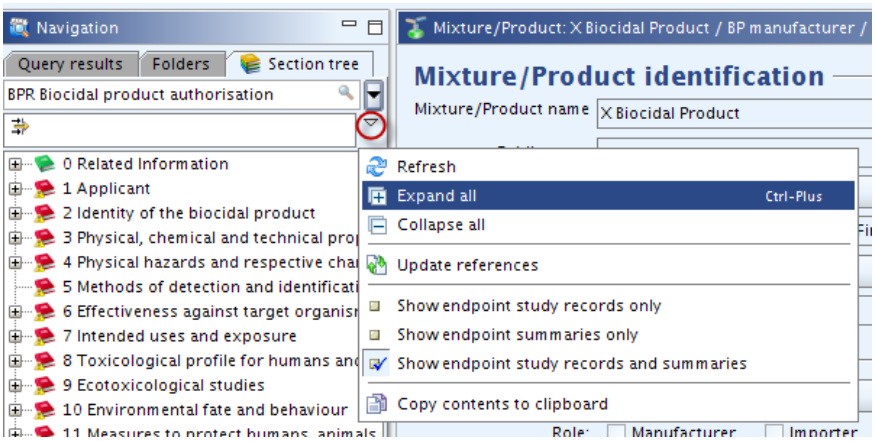
Select the product you would like to edit.



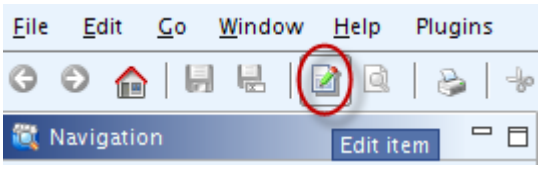
Double click to open a document. The Section tree appears. Make sure you select the 'BPR Biocidal product authorisation' view as illustrated below.


File Edit Go Window Help Plugins
Navigation
Query results Folders Section tree
BPR Biocidal product authorisation
Open list ...
0 Related Information
1 Applicant
2 Identity of the biocidal product
3 Physical, chemical and technical proper
4 Physical hazards and respective charact
5 Methods of detection and identification
6 Effectiveness against target organisms
7 Intended uses and exposure
8 Toxicological profile for humans and ar
9 Ecotoxicological studies
10 Environmental fate and behaviour
11 Measures to protect humans, animals
12 Classification & Labelling and PBT asse
13 Summary and evaluation
Mixture/Product: X Biocidal Product / BP manufacturer
Mixture/Product identification
Mixture/Product name X Biocidal Product
Public name
Legal entity flags
Legal entity BP manufacturer / Helsinki / F
Third party flags
Third party
Role in the supply chain
Role flags
Role: Manufacturer Importer
Other names

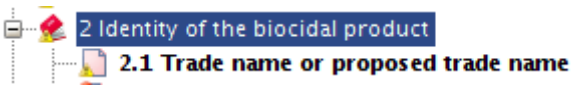
On the left side of the window you can see the sections where the information should be inserted. To see them all, select ‘Expand all’.



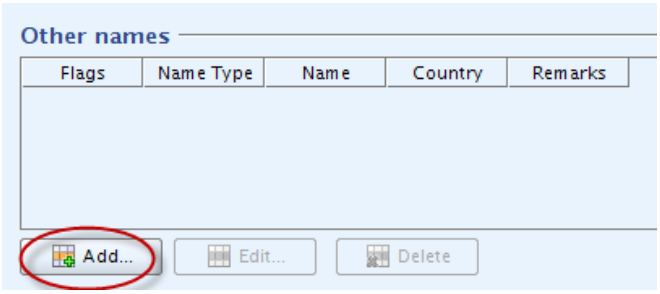
Each time you aim at inserting data in IUCLID, switch to the Edit mode.



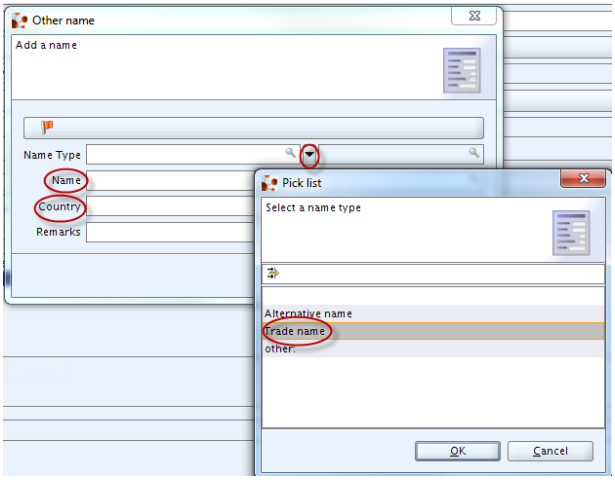
4.2 SPC SECTION 1.1 TRADE NAME OF THE PRODUCT (IUCLID SECTION 2.1)



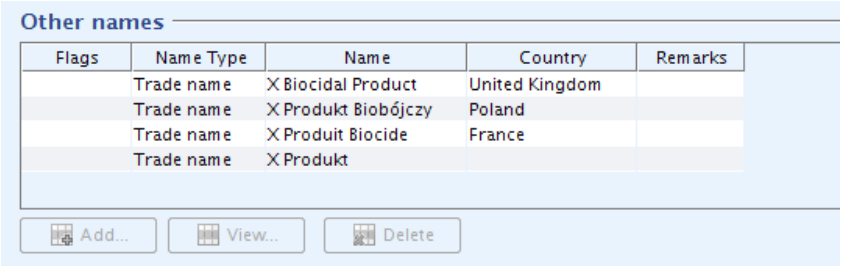
Go to Other names and click Add:



Select Trade name from the picklist Name Type, click OK. Then insert Name. You can also make a selection in the Country list if relevant.



IUCLID data



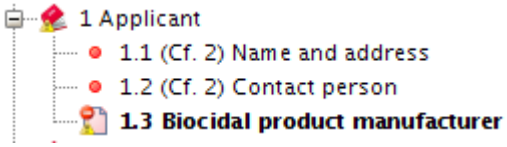
Outcome in the generated SPC

1. Administrative information

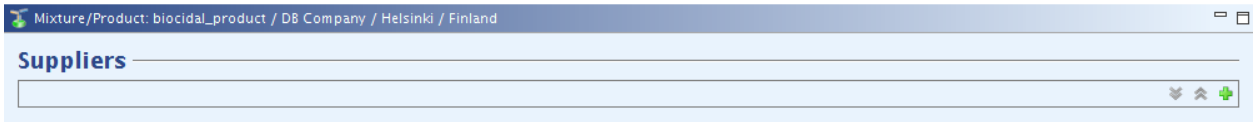
1.1. Trade name of the product

Trade name	Country (if relevant)
X Biocidal Product	United Kingdom
X Produkt Biobójczy	Poland
X Produit Biocide	France
X Produkt	

4.3 SPC SECTION 1.3. MANUFACTURER(S) OF THE PRODUCT (IUCLID SECTION 1.3)

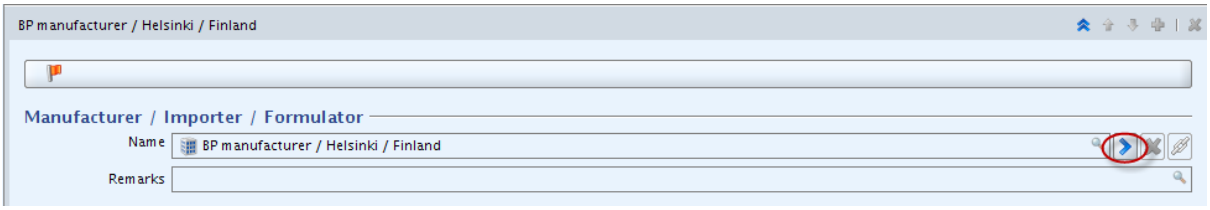


Click to add a record.

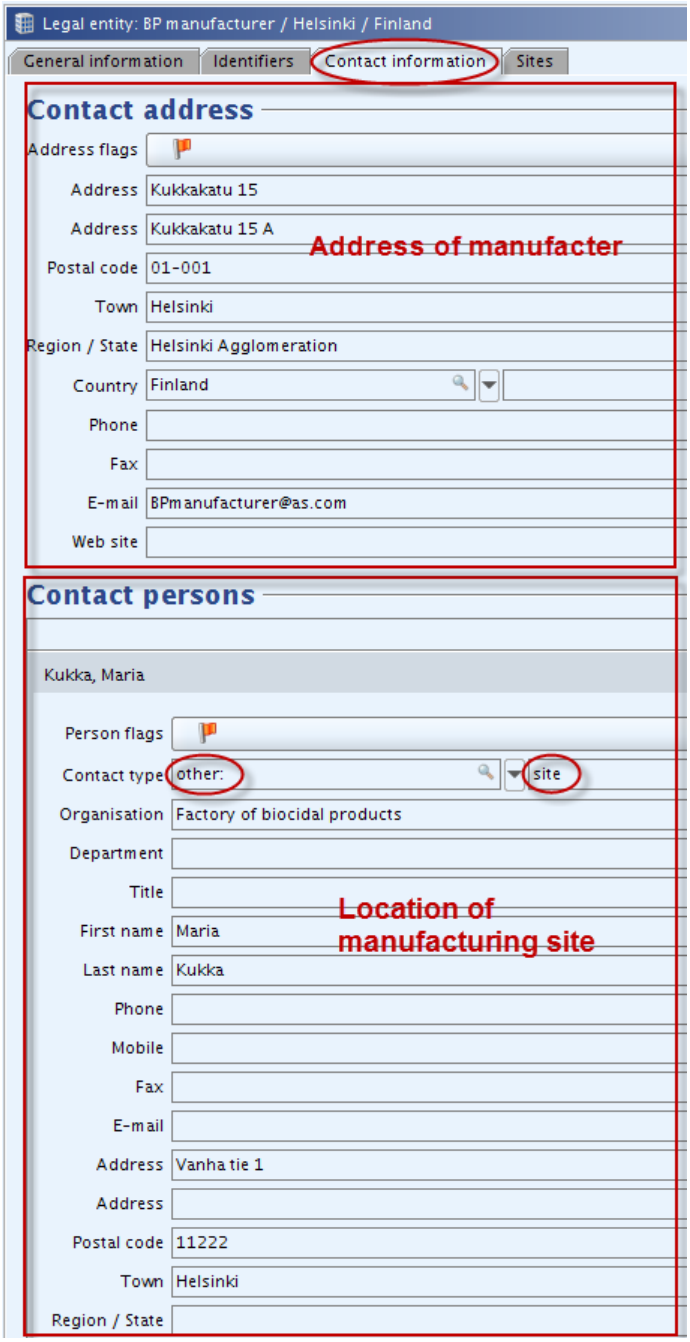


Link a Legal Entity clicking .

Click on blue arrow to open the Legal Entity information and there fill in the information in the tab Contact information if not already available.



IUCLID data


Legal entity: BP manufacturer / Helsinki / Finland
General information
Identifiers
Contact information
Sites
Contact address
Address flags
Address Kukkakatu 15
Address Kukkakatu 15 A
Address of manufacter
Postal code 01-001
Town Helsinki
Region / State Helsinki Agglomeration
Country Finland
Phone
Fax
E-mail BPmanufacturer@as.com
Web site
Contact persons
Kukka, Maria
Person flags
Contact type other: site
Organisation Factory of biocidal products
Department
Title
First name Maria
Location of manufacturing site
Last name Kukka
Phone
Mobile
Fax
E-mail
Address Vanha tie 1
Address
Postal code 11222
Town Helsinki
Region / State

Outcome in the generated SPC

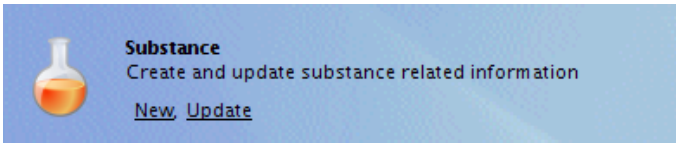
1.3. Manufacturer(s) of the product

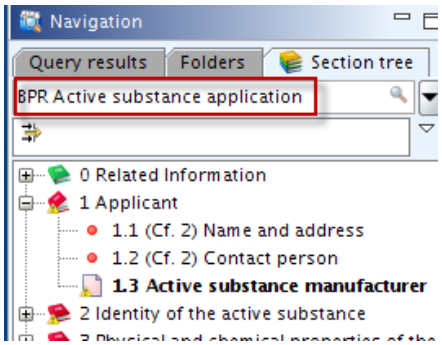
Name of manufacturer	BP manufacturer
Address of manufacturer	Address 1: Kukkakatu 15 Address 2: Kukkakatu 15 A Postal code: 01-001 Town: Helsinki Region/State: Helsinki Agglomeration Country: Finland Fax: E-mail: BPmanufacturer@as.com Web site:
Location of manufacturing sites	Address 1: Vanha tie 1 Address 2: Postal code: 11222 Town: Helsinki Region/State: Country: Finland Fax: E-mail:

4.4 SPC SECTION 1.4. MANUFACTURER (S) OF THE ACTIVE SUBSTANCE(S) (IUCLID SUBSTANCE DATASET, SECTION 1.3)

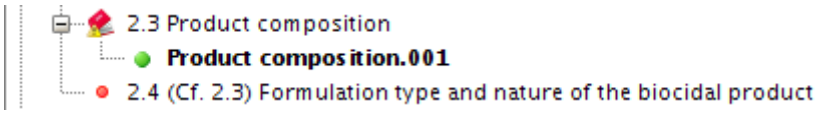
Information on Manufacturer(s) of the active substance(s) is linked to the Legal Entity (Legal Entities) of this (these) substance(s).

The way of inserting data is similar to the one described in chapter 4.1., for a biocidal product manufacturer, but the insertion of data should start in section 1.3 of the active substance dataset.





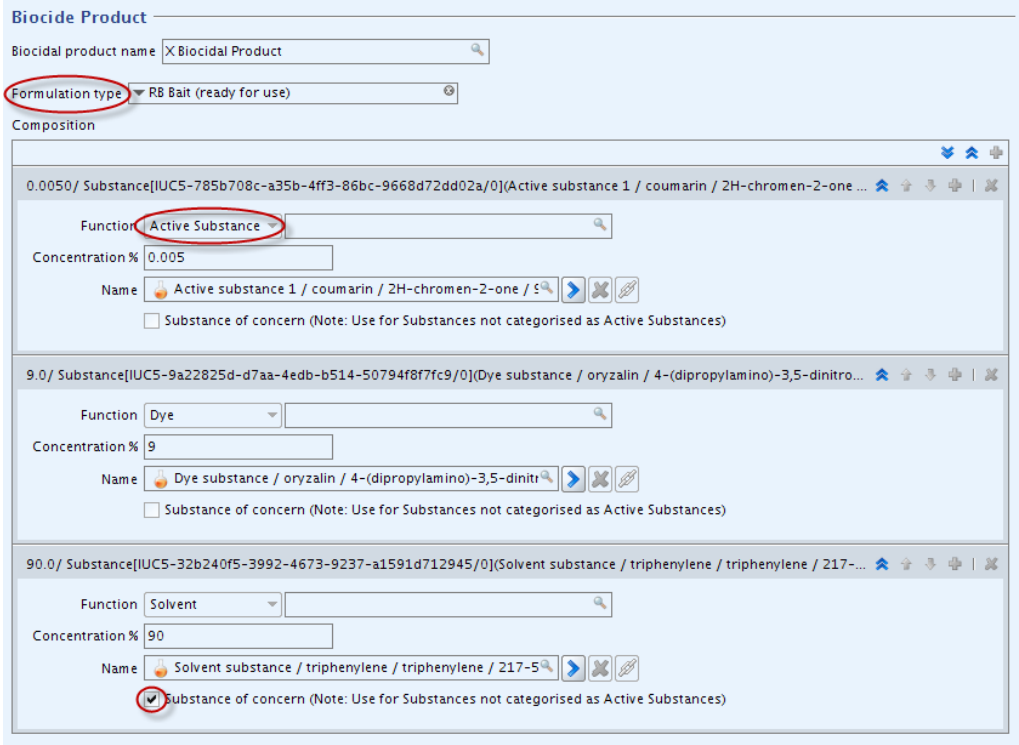
4.5 SPC SECTION 2. PRODUCT COMPOSITION AND FORMULATION (IUCLID SECTION 2.3)



Note: The small dot next to section 2.4 means the visual link between section 2.4 and 2.3. Therefore the information on formulation type should be inserted in section 2.3. To see detailed guide how to create the composition of the biocidal product please refer to the BPR dossier creation IUCLID Quick Guide on the IUCLID website.

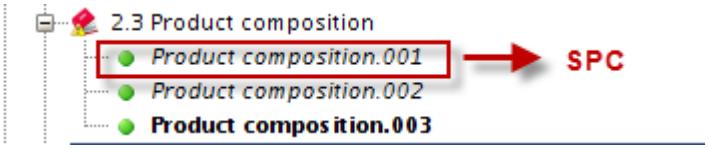
http://www.iuclid.eu/index.php?fuseaction=home.documentation#bprmanual

IUCLID data

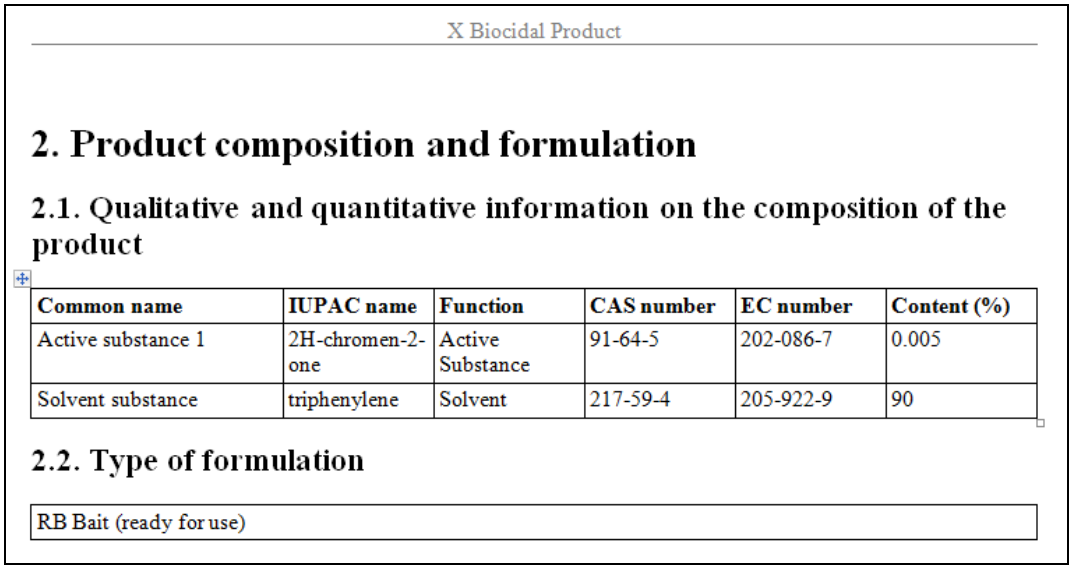

Biocide Product
Biocidal product name X Biocidal Product
Formulation type RB Bait (ready for use)
Composition
0.0050/ Substance[IUC5-785b708c-a35b-4ff3-86bc-9668d72dd02a/0](Active substance 1 / coumarin / 2H-chromen-2-one ...
Function Active Substance
Concentration % 0.005
Name Active substance 1 / coumarin / 2H-chromen-2-one / 9
Substance of concern (Note: Use for Substances not categorised as Active Substances)
9.0/ Substance[IUC5-9a22825d-d7aa-4edb-b514-50794f8f7fc9/0](Dye substance / oryzalin / 4-(dipropylamino)-3,5-dinitro...
Function Dye
Concentration % 9
Name Dye substance / oryzalin / 4-(dipropylamino)-3,5-dinitr
Substance of concern (Note: Use for Substances not categorised as Active Substances)
90.0/ Substance[IUC5-32b240f5-3992-4673-9237-a1591d712945/0](Solvent substance / triphenylene / triphenylene / 217-...
Function Solvent
Concentration % 90
Name Solvent substance / triphenylene / triphenylene / 217-5
Substance of concern (Note: Use for Substances not categorised as Active Substances)

Only one biocidal product composition endpoint is allowed for a single biocidal product dataset.

Please note that if there is more than one endpoint in section 2.3 Biocidal product composition, only the first block will be transferred to the SPC. The generation of SPC for an entire product family is not supported by the Report Generator.



Outcome in the generated SPC



X Biocidal Product

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the product

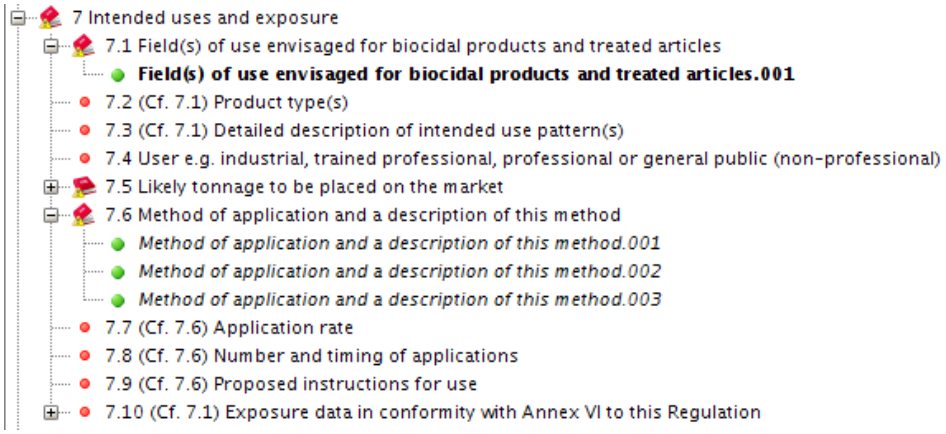
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active substance 1	2H-chromen-2-one	Active Substance	91-64-5	202-086-7	0.005
Solvent substance	triphenylene	Solvent	217-59-4	205-922-9	90

2.2. Type of formulation

RB Bait (ready for use)

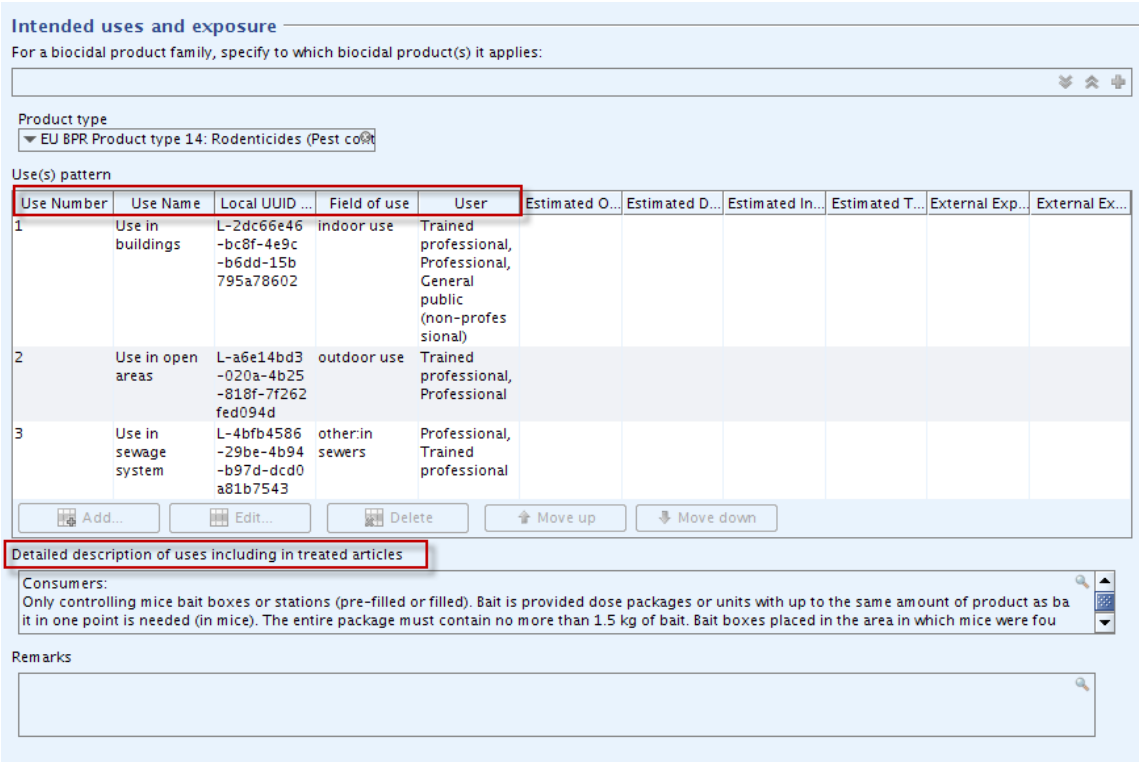
Finally note that in the current version of the Report Generator only information related to the active substance(s) and the substance(s) of concern are transferred to the SPC document.

4.6 SPC SECTION 3. AUTHORISED USE(S) (IUCLID SECTIONS 7.1 AND 7.6)

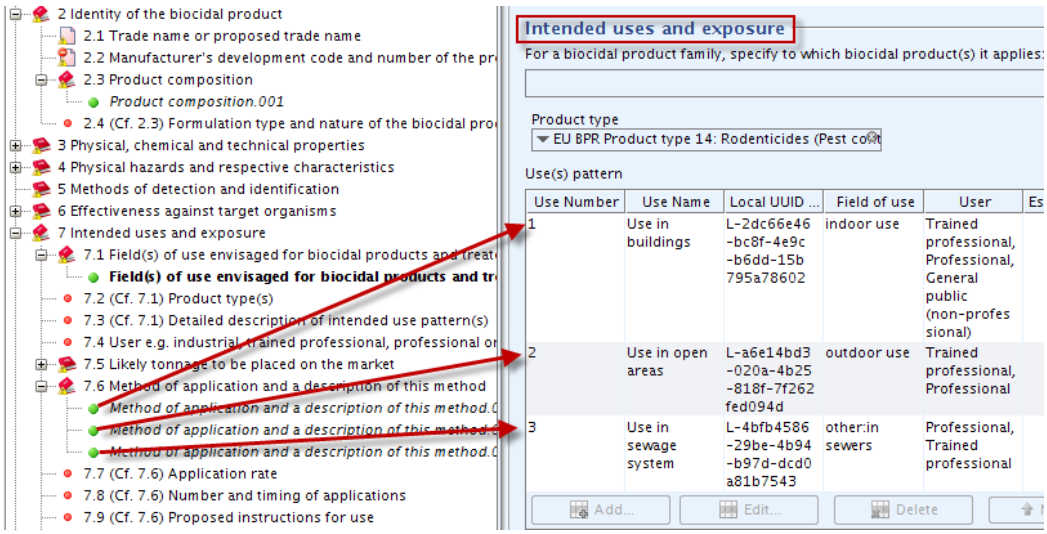

7 Intended uses and exposure
7.1 Field(s) of use envisaged for biocidal products and treated articles
Field(s) of use envisaged for biocidal products and treated articles.001
7.2 (Cf. 7.1) Product type(s)
7.3 (Cf. 7.1) Detailed description of intended use pattern(s)
7.4 User e.g. industrial, trained professional, professional or general public (non-professional)
7.5 Likely tonnage to be placed on the market
7.6 Method of application and a description of this method
Method of application and a description of this method.001
Method of application and a description of this method.002
Method of application and a description of this method.003
7.7 (Cf. 7.6) Application rate
7.8 (Cf. 7.6) Number and timing of applications
7.9 (Cf. 7.6) Proposed instructions for use
7.10 (Cf. 7.1) Exposure data in conformity with Annex VI to this Regulation

Note: The small dots next to some sections, e.g. 7.2 or 7.3 mean the visual link between these sections and section mentioned in the brackets (7.1). Therefore the information related to these sections should be inserted in the section mentioned between brackets.

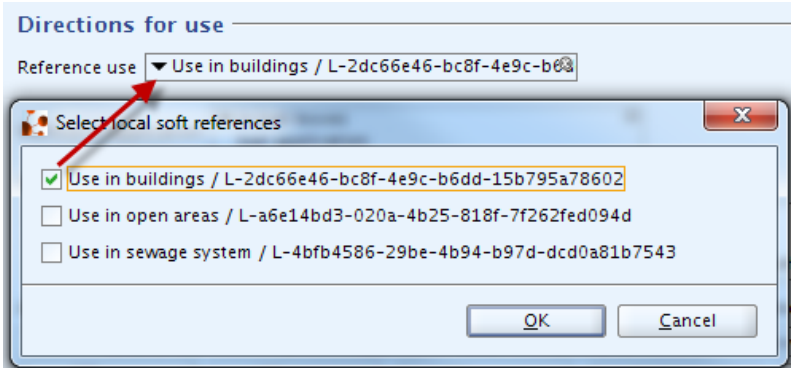
The fields that have to be filled in IUCLID section 7.1 to be transferred to the draft SPC are marked in red in the screenshot below.


Intended uses and exposure
For a biocidal product family, specify to which biocidal product(s) it applies:
Product type
EU BPR Product type 14: Rodenticides (Pest co
Use(s) pattern
Use Number | Use Name | Local UUID ... | Field of use | User | Estimated O... | Estimated D... | Estimated In... | Estimated T... | External Exp... | External Ex...
1 | Use in buildings | L-2dc66e46-bc8f-4e9c-b6dd-15b795a78602 | indoor use | Trained professional, Professional, General public (non-professional)
2 | Use in open areas | L-a6e14bd3-020a-4b25-818f-7f262fed094d | outdoor use | Trained professional, Professional
3 | Use in sewage system | L-4bfb4586-29be-4b94-b97d-dcd0a81b7543 | other:in sewers | Professional, Trained professional
Add... Edit... Delete Move up Move down
Detailed description of uses including in treated articles
Consumers:
Only controlling mice bait boxes or stations (pre-filled or filled). Bait is provided dose packages or units with up to the same amount of product as ba
it in one point is needed (in mice). The entire package must contain no more than 1.5 kg of bait. Bait boxes placed in the area in which mice were fou
Remarks

Each row in the above displayed table (i.e. each use) should have its corresponding endpoint study record in section 7.6.

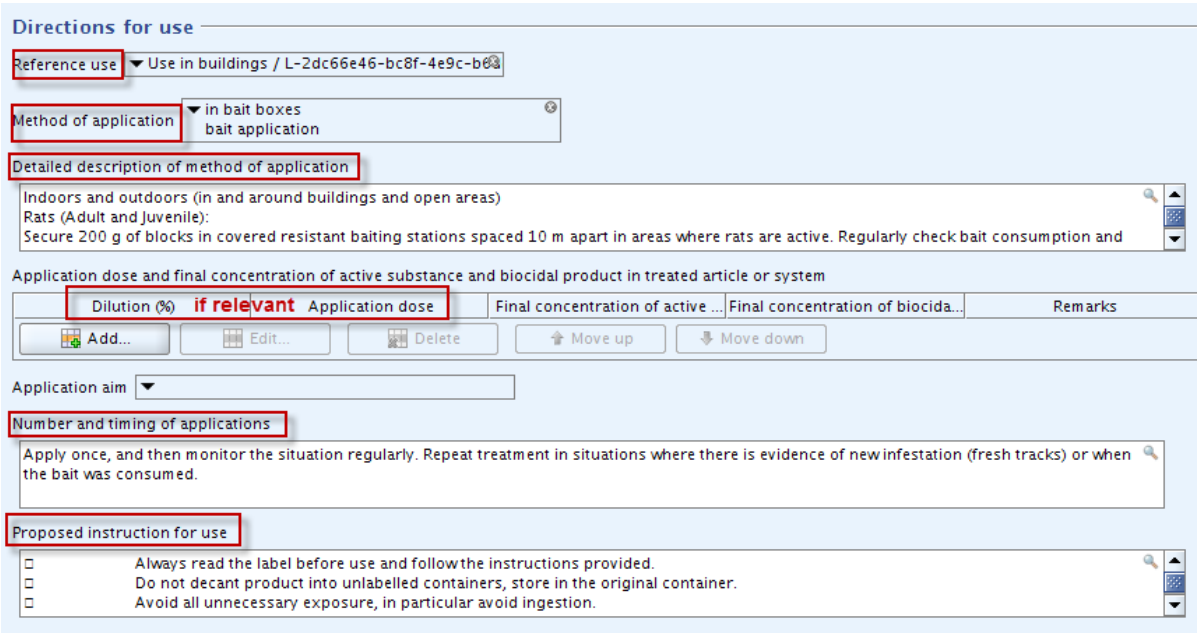

2 Identity of the biocidal product
2.1 Trade name or proposed trade name
2.2 Manufacturer's development code and number of the pr
2.3 Product composition
Product composition.001
2.4 (Cf. 2.3) Formulation type and nature of the biocidal pro
3 Physical, chemical and technical properties
4 Physical hazards and respective characteristics
5 Methods of detection and identification
6 Effectiveness against target organisms
7 Intended uses and exposure
7.1 Field(s) of use envisaged for biocidal products and treat
Field(s) of use envisaged for biocidal products and tr
7.2 (Cf. 7.1) Product type(s)
7.3 (Cf. 7.1) Detailed description of intended use pattern(s)
7.4 User e.g. industrial, trained professional, professional or
7.5 Likely tonnage to be placed on the market
7.6 Method of application and a description of this method
Method of application and a description of this method.0
Method of application and a description of this method.
Method of application and a description of this method.0
7.7 (Cf. 7.6) Application rate
7.8 (Cf. 7.6) Number and timing of applications
7.9 (Cf. 7.6) Proposed instructions for use
Intended uses and exposure
For a biocidal product family, specify to which biocidal product(s) it applies:
Product type
EU BPR Product type 14: Rodenticides (Pest co
Use(s) pattern
Use Number | Use Name | Local UUID ... | Field of use | User | Es
1 | Use in buildings | L-2dc66e46-bc8f-4e9c-b6dd-15b795a78602 | indoor use | Trained professional, Professional, General public (non-professional)
2 | Use in open areas | L-a6e14bd3-020a-4b25-818f-7f262fed094d | outdoor use | Trained professional, Professional
3 | Use in sewage system | L-4bfb4586-29be-4b94-b97d-dcd0a81b7543 | other:in sewers | Professional, Trained professional
Add... Edit... Delete

In each document of section 7.6 there is an indication to which use(s) this very specific endpoint relates to.

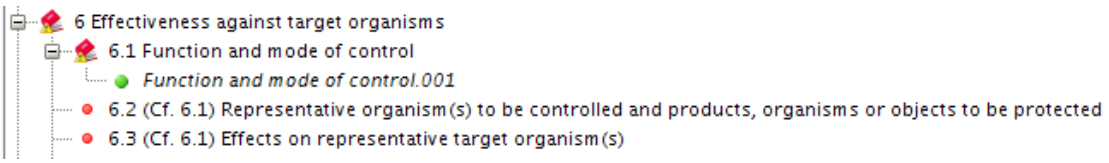


If the all content of the section 7.6 is the same for more than one use, then the endpoint can be linked to several relevant uses.

The fields that have to be filled-in in IUCLID section 7.6 to be transferred to the draft SPC are marked in red on the screenshot below.

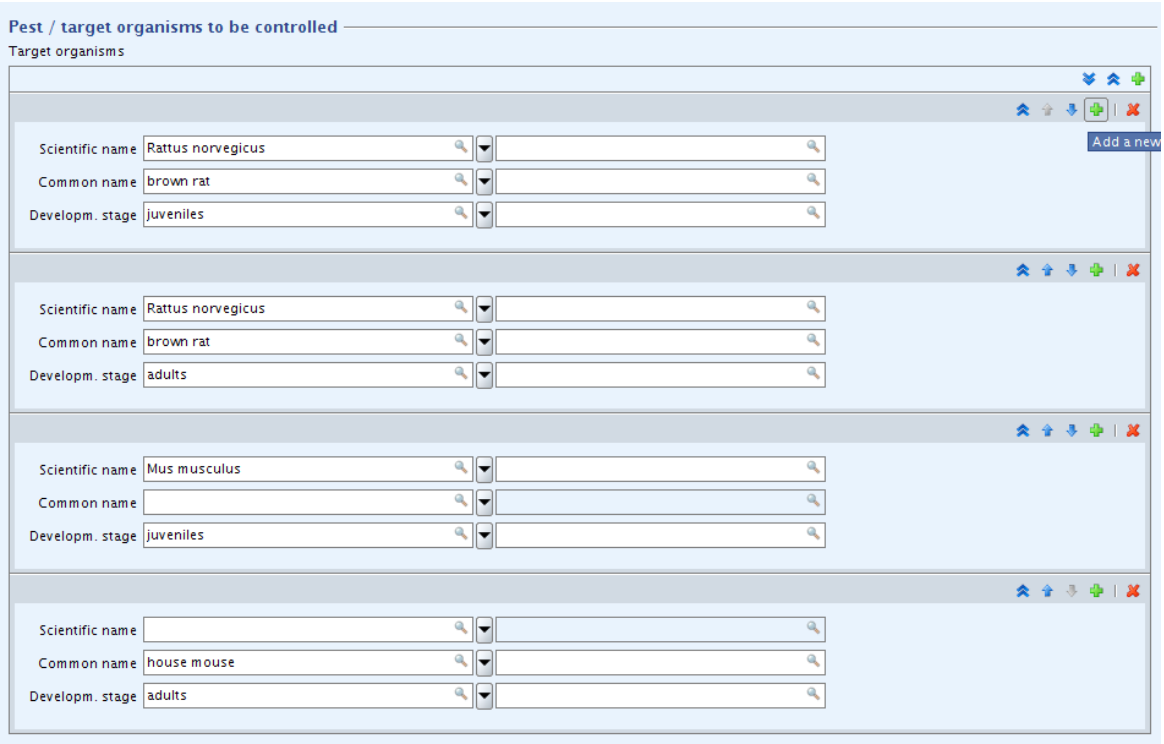

Directions for use
Reference use
Use in buildings / L-2dc66e46-bc8f-4e9c-b6
Method of application
in bait boxes
bait application
Detailed description of method of application
Indoors and outdoors (in and around buildings and open areas)
Rats (Adult and Juvenile):
Secure 200 g of blocks in covered resistant baiting stations spaced 10 m apart in areas where rats are active. Regularly check bait consumption and
Application dose and final concentration of active substance and biocidal product in treated article or system
Dilution (%)
if relevant
Application dose
Final concentration of active ...
Final concentration of biocida...
Remarks
Add...
Edit...
Delete
Move up
Move down
Application aim
Number and timing of applications
Apply once, and then monitor the situation regularly. Repeat treatment in situations where there is evidence of new infestation (fresh tracks) or when the bait was consumed.
Proposed instruction for use
Always read the label before use and follow the instructions provided.
Do not decant product into unlabelled containers, store in the original container.
Avoid all unnecessary exposure, in particular avoid ingestion.

4.7 IUCLID SECTION 6.1 (TARGET ORGANISMS)


6 Effectiveness against target organisms
6.1 Function and mode of control
Function and mode of control.001
6.2 (Cf. 6.1) Representative organism(s) to be controlled and products, organisms or objects to be protected
6.3 (Cf. 6.1) Effects on representative target organism(s)

Note: The small dot next to section 6.3 means the visual link between this section and section mentioned in brackets (6.1). Therefore the information related to target organism(s) should be inserted in section 6.1.

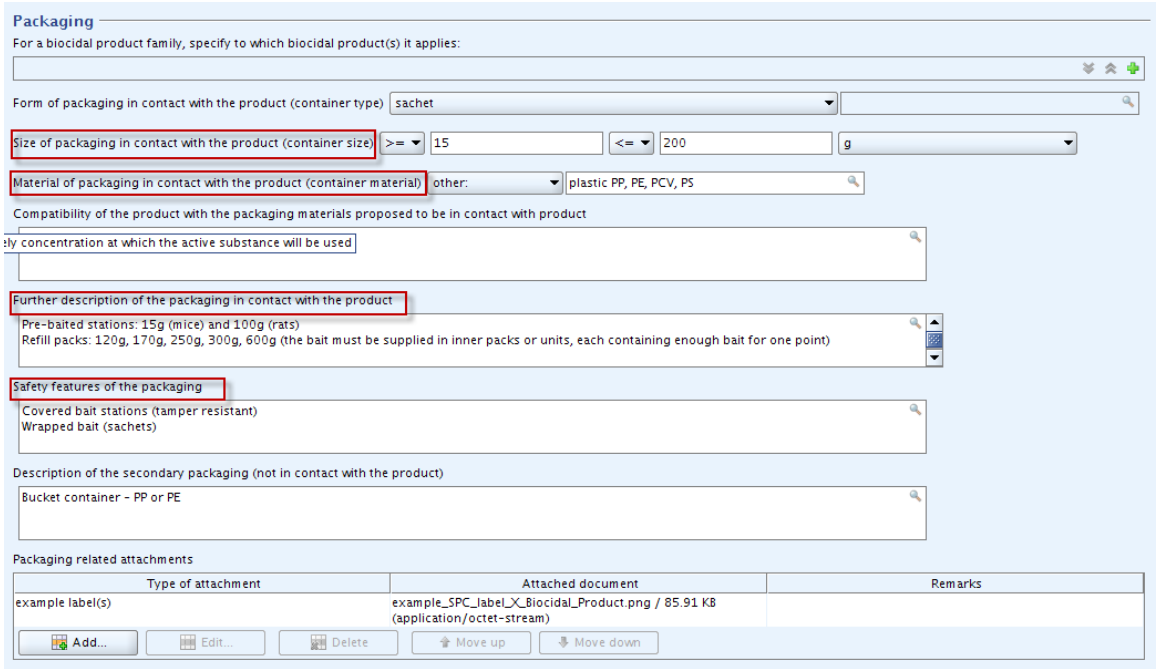
IUCLID data



To add new blocks, the user needs to click .

4.8 IUCLID SECTION 12 (PACKAGING INFORMATION)

The fields that have to be filled in IUCLID section 12 for the packaging before the generation of the SPC are marked in red on the screen shot below.


Packaging
For a biocidal product family, specify to which biocidal product(s) it applies:
Form of packaging in contact with the product (container type) sachet
Size of packaging in contact with the product (container size) >= 15 <= 200 g
Material of packaging in contact with the product (container material) other: plastic PP, PE, PCV, PS
Compatibility of the product with the packaging materials proposed to be in contact with product
ly concentration at which the active substance will be used
Further description of the packaging in contact with the product
Pre-baited stations: 15g (mice) and 100g (rats)
Refill packs: 120g, 170g, 250g, 300g, 600g (the bait must be supplied in inner packs or units, each containing enough bait for one point)
Safety features of the packaging
Covered bait stations (tamper resistant)
Wrapped bait (sachets)
Description of the secondary packaging (not in contact with the product)
Bucket container - PP or PE
Packaging related attachments
Type of attachment
Attached document
Remarks
example label(s)
example_SPC_label_X_Biocidal_Product.png / 85.91 KB
(application/octet-stream)
Add...
Edit...
Delete
Move up
Move down

Outcome in the generated SPC (the content of some rows in the example below was truncated).

3. Authorised use(s)

Table 1. Use # 1 - Use in buildings

Product Type	EU BPR Product type 14: Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Consumers: Only controlling mice bait boxes or stations (pre-filled or filled). Bait is provided dose packages or units with up to the same amount of product as bait in one point is needed (in mice). The entire package must contain no more than 1.5 kg of bait. Bait boxes placed in the area in which mice were found. Bait boxes are preferable to fixed to the floor or other surface. Use
Target organism (including development stage)	Scientific name: Rattus norvegicus, common name: brown rat, development stage: juveniles Scientific name: Rattus norvegicus, common name: brown rat, development stage: adults Scientific name: Mus musculus, common name: , development stage: juveniles Scientific name: , common name: house mouse, development stage: adults
Field of use	indoor use
Application method(s)	**Method of application:** in bait boxes;bait application **Detailed description of the method:** Indoors and outdoors (in and around buildings and open areas) Rats (Adult and Juvenile): Secure 200 g of blocks in covered resistant baiting stations spaced 10 m apart in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (fresh tracks). Mice (Adult and Juvenile): Secure 20-30g of blocks, in covered, tamper resistant baiting stations spaced
Application rate(s) and frequency	**Number and timing of application:** Apply once, and then monitor the situation regularly. Repeat treatment in situations where there is evidence of new infestation (fresh tracks) or when the bait was consumed.
Category(ies) of users	Trained professional Professional General public (non-professional)
Pack sizes and packaging material	**Pack size is:**>= 15 — <= 200 g **, and the packaging material is** plastic PP, PE, PCV, PS **Further description of the packaging:** Pre-baited stations: 15g (mice) and 100g (rats) Refill packs: 120g, 170g, 250g, 300g, 600g (the bait must be supplied in inner packs or units, each containing enough bait for one point) **Safety features:** Covered bait stations (tamper resistant) Wrapped bait (sachets)

Each use from section 7.1 has its own table. The title of the table is composed of the use number and the use name.

Please note that there is no link established between section containing information on target organisms (6.1), section containing information on the packaging (12.4) and the uses in section 7.1. Therefore information on all target organisms and packaging will be repeated for each use in the draft SPC. Please ensure that the content specific to each use is inserted only to the relevant table, by adapting it manually. The detailed instruction concerning the content of this SPC section is also displayed in the generated SPC, as a NOTE.

NOTE: In case that there is more than one row in the table 'Use(s) pattern' or more than one endpoint in section 7.1 Field(s) of uses envisaged for biocidal products and treated articles, the following items have been retrieved for each use in each endpoint to the relevant table (one table – one use):

- Product type (the same for all uses in one endpoint)
- Where relevant, an exact description of the authorised use (the same description for all uses in one endpoint, might be adapted manually to each use if needed)
- Field of use
- Category(ies) of users

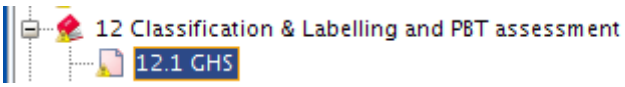
The following items, belonging to section 7.6 Method of application and a description of this method, have been retrieved accordingly to the link between section 7.6 and 7.1 (reference use) to the relevant table (one table – one use):

- Application method(s)
- Application rate(s) and frequency

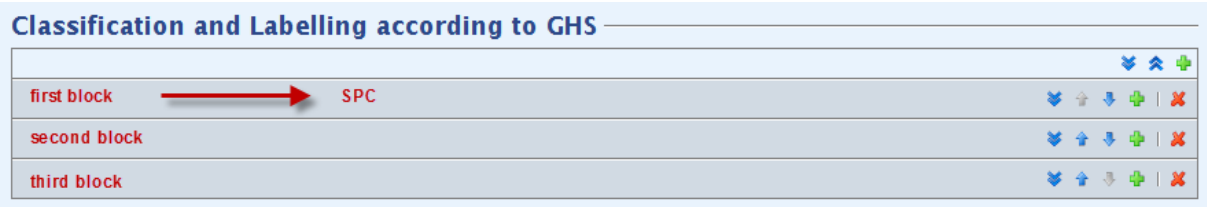
For the following items, the content provided to all tables (for all endpoints) will be the same. Therefore, please ensure that the content specific to each use is inserted to the relevant table, by adapting it manually:

- Target organism (including development stage)
- Pack sizes and packaging material]

4.9 SPC SECTION 4.1. CLASSIFICATION AND LABELLING OF THE PRODUCT ACCORDING TO THE REGULATION (EC) 1272/2008 (IUCLID SECTION 12.1 AND 12.2)

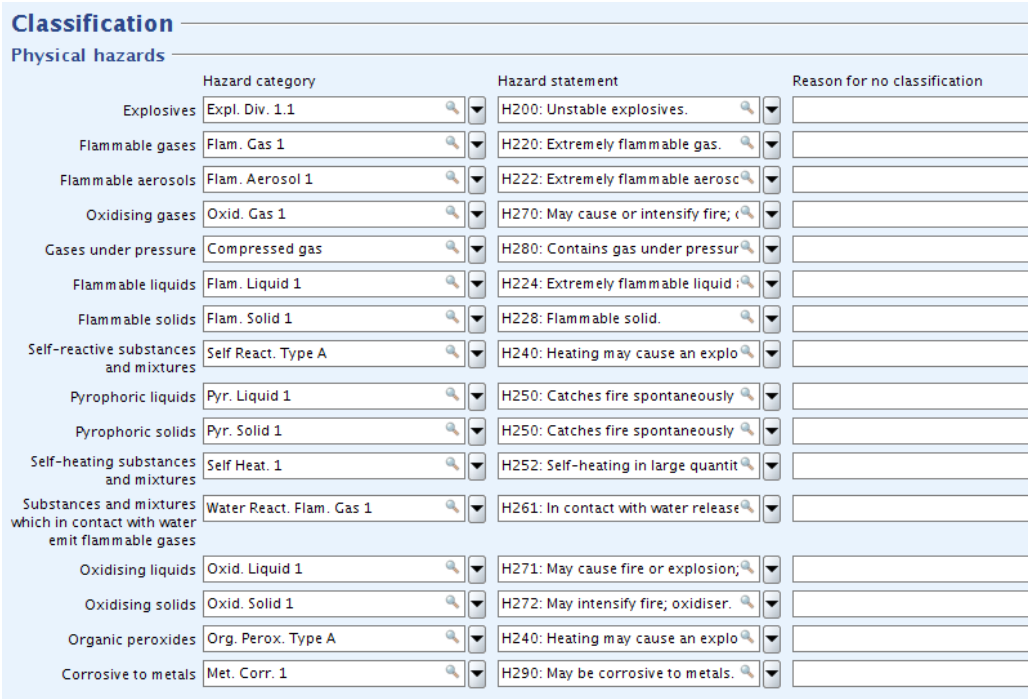


Please note that if there is more than one endpoint in section 12.1 GHS, only the first block will be transferred to the draft SPC.



An example of the data transferred from section 12.1 to the SPC has been divided in seven smaller parts below.

IUCLID data (1)



Classification

Physical hazards

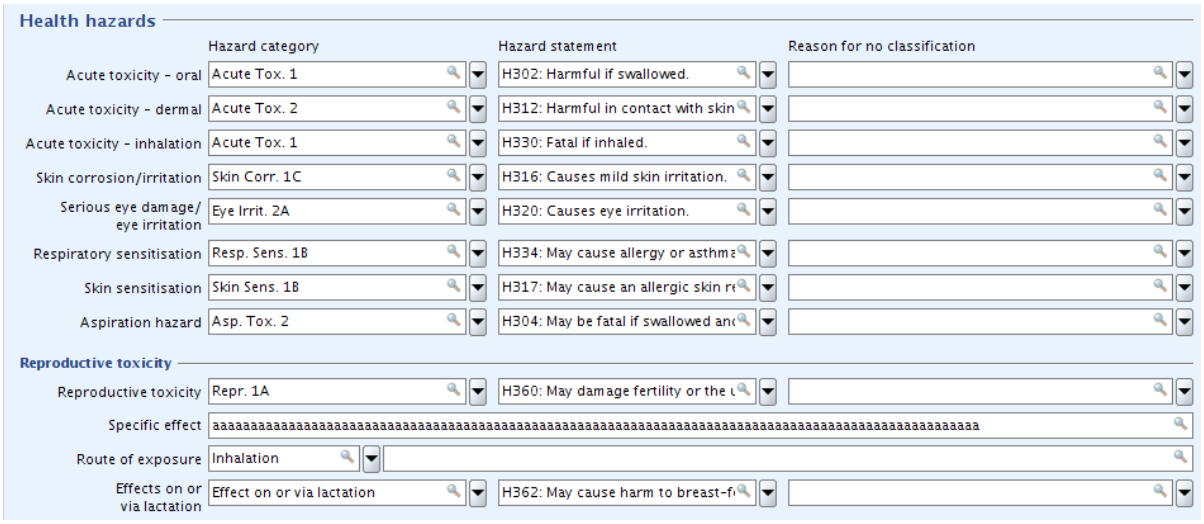
	Hazard category	Hazard statement	Reason for no classification
Explosives	Expl. Div. 1.1	H200: Unstable explosives.	
Flammable gases	Flam. Gas 1	H220: Extremely flammable gas.	
Flammable aerosols	Flam. Aerosol 1	H222: Extremely flammable aerosc	
Oxidising gases	Oxid. Gas 1	H270: May cause or intensify fire; (	
Gases under pressure	Compressed gas	H280: Contains gas under pressur	
Flammable liquids	Flam. Liquid 1	H224: Extremely flammable liquid	
Flammable solids	Flam. Solid 1	H228: Flammable solid.	
Self-reactive substances and mixtures	Self React. Type A	H240: Heating may cause an explo	
Pyrophoric liquids	Pyr. Liquid 1	H250: Catches fire spontaneously	
Pyrophoric solids	Pyr. Solid 1	H250: Catches fire spontaneously	
Self-heating substances and mixtures	Self Heat. 1	H252: Self-heating in large quantit	
Substances and mixtures which in contact with water emit flammable gases	Water React. Flam. Gas 1	H261: In contact with water release	
Oxidising liquids	Oxid. Liquid 1	H271: May cause fire or explosion;	
Oxidising solids	Oxid. Solid 1	H272: May intensify fire; oxidiser.	
Organic peroxides	Org. Perox. Type A	H240: Heating may cause an explo	
Corrosive to metals	Met. Corr. 1	H290: May be corrosive to metals.	

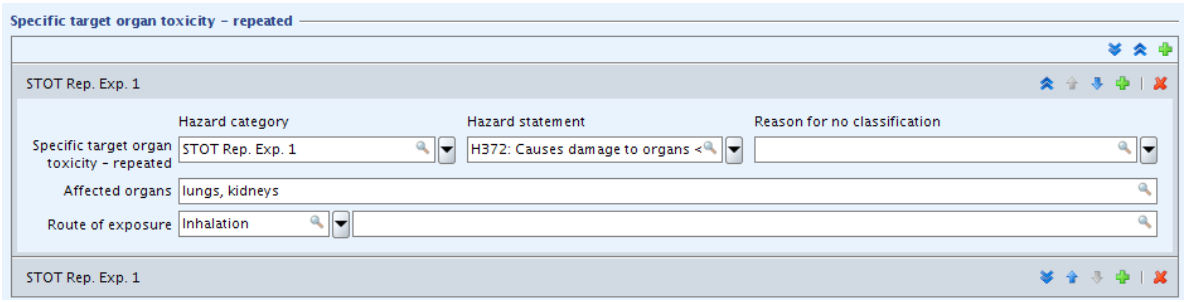
Outcome in the generated SPC (1)

Table 4. Classification and labelling according to CLP/GHS for physicochemical properties

Hazard class	Hazard category	Hazard statement
Explosives:	Expl. Div. 1.1	H200: Unstable explosives.
Flammable gases:	Flam. Gas 1	H220: Extremely flammable gas.
Flammable aerosols:	Flam. Aerosol 1	H222: Extremely flammable aerosol.
Oxidising gases:	Oxid. Gas 1	H270: May cause or intensify fire; oxidiser.
Gases under pressure:	Compressed gas	H280: Contains gas under pressure; may explode if heated.
Flammable liquids:	Flam. Liquid 1	H224: Extremely flammable liquid and vapour.
Flammable solids:	Flam. Solid 1	H228: Flammable solid.
Self-reactive substances and mixtures:	Self React. Type A	H240: Heating may cause an explosion.
Pyrophoric liquids:	Pyr. Liquid 1	H250: Catches fire spontaneously if exposed to air.
Pyrophoric solids:	Pyr. Solid 1	H250: Catches fire spontaneously if exposed to air.
Self-heating substances and mixtures:	Self Heat. 1	H252: Self-heating in large quantities; may catch fire.
Substances and mixtures which in contact with water emit flammable gases:	Water React. Flam. Gas 1	H261: In contact with water releases flammable gases.
Oxidising liquids:	Oxid. Liquid 1	H271: May cause fire or explosion; strong oxidiser.
Oxidising solids:	Oxid. Solid 1	H272: May intensify fire; oxidiser.
Organic peroxides:	Org. Perox. Type A	H240: Heating may cause an explosion.
Corrosive to metals:	Met. Corr. 1	H290: May be corrosive to metals.

IUCLID data (2)


Health hazards
Hazard category
Hazard statement
Reason for no classification
Acute toxicity - oral
Acute Tox. 1
H302: Harmful if swallowed.
Acute toxicity - dermal
Acute Tox. 2
H312: Harmful in contact with skin
Acute toxicity - inhalation
Acute Tox. 1
H330: Fatal if inhaled.
Skin corrosion/irritation
Skin Corr. 1C
H316: Causes mild skin irritation.
Serious eye damage/ eye irritation
Eye Irrit. 2A
H320: Causes eye irritation.
Respiratory sensitisation
Resp. Sens. 1B
H334: May cause allergy or asthma
Skin sensitisation
Skin Sens. 1B
H317: May cause an allergic skin re
Aspiration hazard
Asp. Tox. 2
H304: May be fatal if swallowed and
Reproductive toxicity
Reproductive toxicity
Repr. 1A
H360: May damage fertility or the u
Specific effect
aaaa

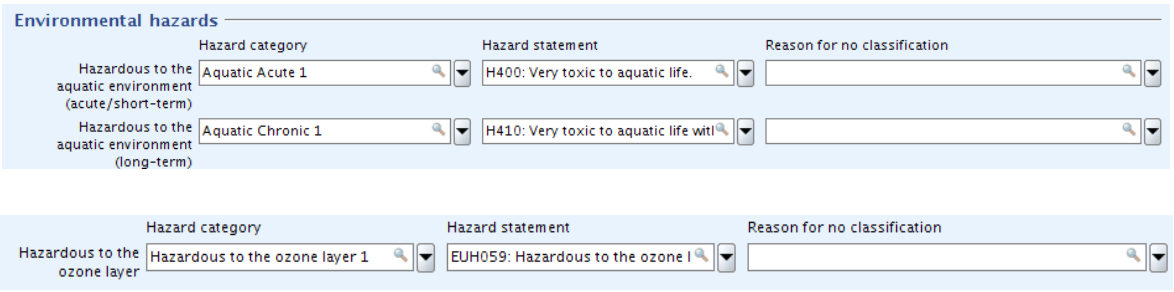


Outcome in the generated SPC (2)

Table 5. Classification and labelling according to CLP/GHS for health hazards

Hazard class	Hazard category	Hazard statement
Acute toxicity - oral:	Acute Tox. 1	H302: Harmful if swallowed.
Acute toxicity - dermal:	Acute Tox. 2	H312: Harmful in contact with skin.
Acute toxicity - inhalation:	Acute Tox. 1	H330: Fatal if inhaled.
Skin corrosion / irritation:	Skin Corr. 1C	H316: Causes mild skin irritation.
Serious damage / eye irritation:	Eye Irrit. 2A	H320: Causes eye irritation.
Respiratory sensitisation:	Resp. Sens. 1B	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitisation:	Skin Sens. 1B	H317: May cause an allergic skin reaction.
Aspiration hazard:	Asp. Tox. 2	H304: May be fatal if swallowed and enters airways.
Reproductive Toxicity:	Repr. 1A Specific effect: aaaa

IUCLID data (3)

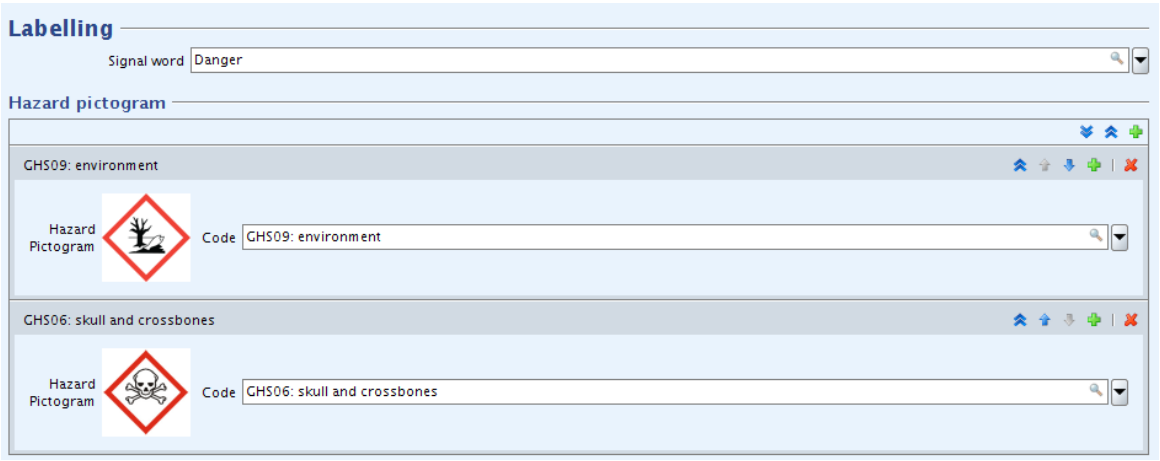

Environmental hazards
Hazard category
Hazard statement
Reason for no classification
Hazardous to the aquatic environment (acute/short-term)
Aquatic Acute 1
H400: Very toxic to aquatic life.
Hazardous to the aquatic environment (long-term)
Aquatic Chronic 1
H410: Very toxic to aquatic life witl
Hazard category
Hazard statement
Reason for no classification
Hazardous to the ozone layer
Hazardous to the ozone layer 1
EUH059: Hazardous to the ozone l

Outcome in the generated SPC (3)

Table 6. Classification and labelling according to CLP/GHS for the environment

Hazard class	Hazard category	Hazard statement
Hazards to the aquatic environment (acute / short-term):	Aquatic Acute 1	H400: Very toxic to aquatic life.
Hazards to the aquatic environment (chronic / long-term):	Aquatic Chronic 1	H410: Very toxic to aquatic life with long lasting effects.
Hazardous to the ozone layer:	Hazardous to the ozone layer 1	EUH059: Hazardous to the ozone layer.

IUCLID data (4)

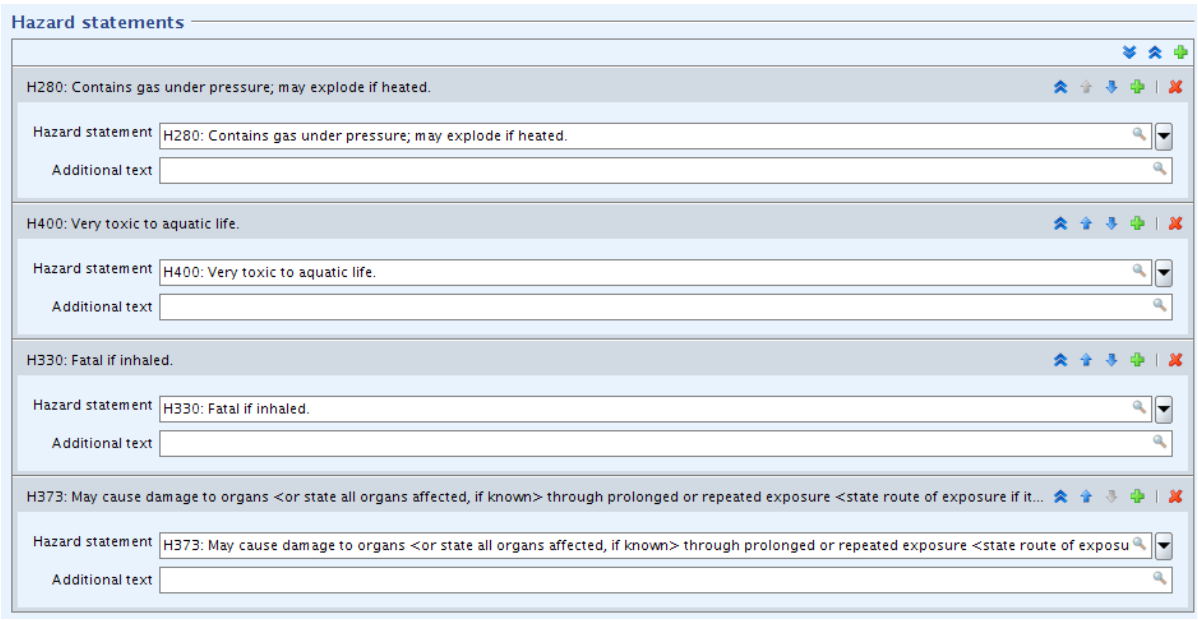


Outcome in the generated SPC (4)

Signal word: Danger

Hazard pictogram:
GHS09: environment
GHS06: skull and crossbones

IUCLID data (5)

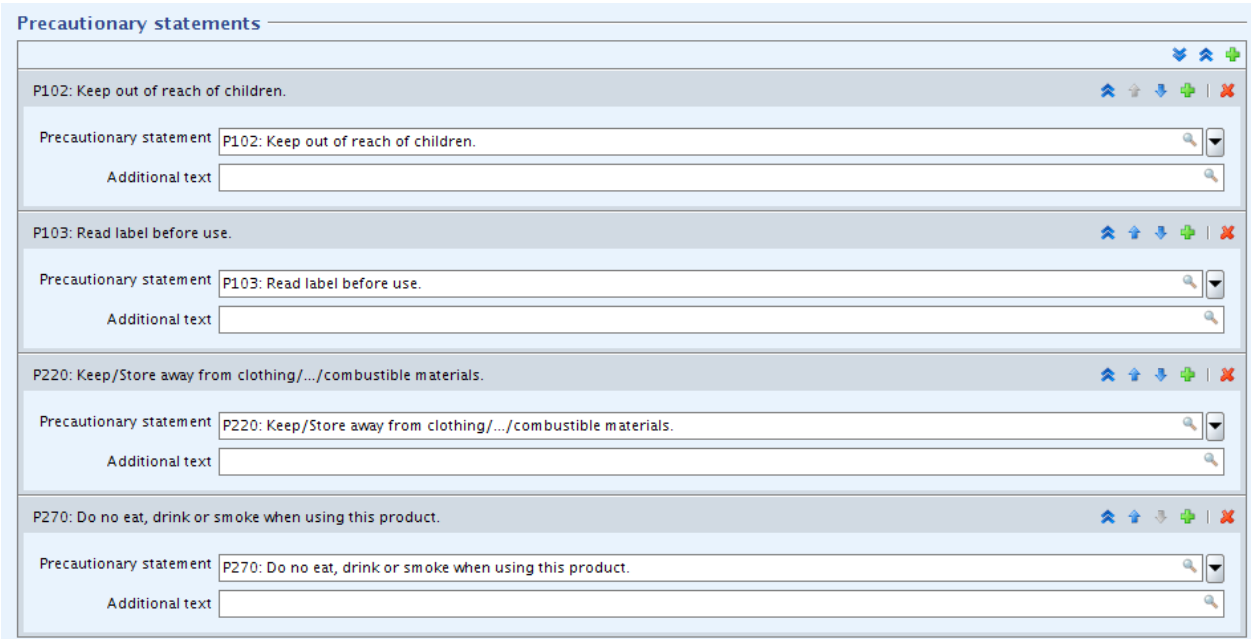

Hazard statements
H280: Contains gas under pressure; may explode if heated.
Hazard statement
H280: Contains gas under pressure; may explode if heated.
Additional text
H400: Very toxic to aquatic life.
Hazard statement
H400: Very toxic to aquatic life.
Additional text
H330: Fatal if inhaled.
Hazard statement
H330: Fatal if inhaled.
Additional text
H373: May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it...
Hazard statement
H373: May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposu
Additional text

Outcome in the generated SPC (5)

Hazard statements:

H280: Contains gas under pressure; may explode if heated.
H400: Very toxic to aquatic life.
H330: Fatal if inhaled.
H373: May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

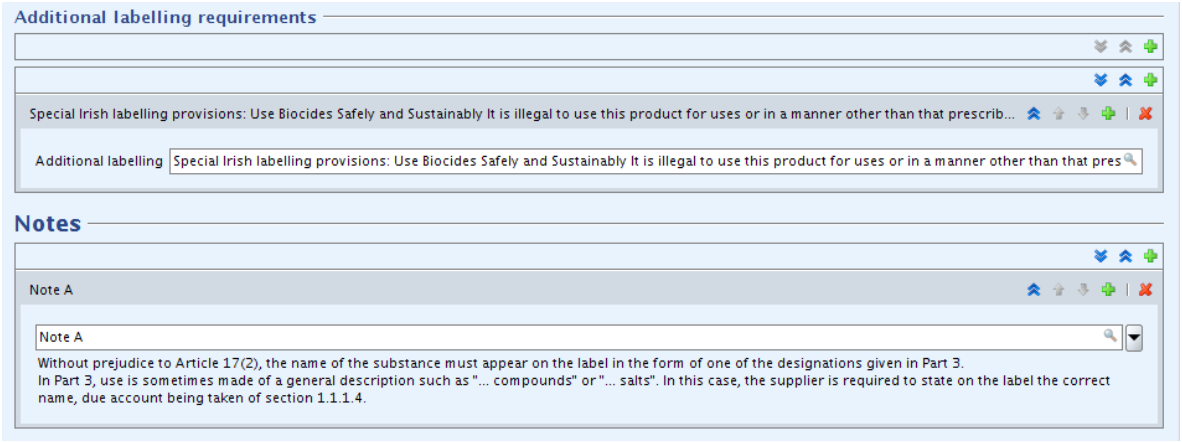
IUCLID data (6)


Precautionary statements
P102: Keep out of reach of children.
Precautionary statement
P102: Keep out of reach of children.
Additional text
P103: Read label before use.
Precautionary statement
P103: Read label before use.
Additional text
P220: Keep/Store away from clothing/.../combustible materials.
Precautionary statement
P220: Keep/Store away from clothing/.../combustible materials.
Additional text
P270: Do no eat, drink or smoke when using this product.
Precautionary statement
P270: Do no eat, drink or smoke when using this product.
Additional text

Outcome in the generated SPC (6)

Precautionary statements:
P102: Keep out of reach of children.
P103: Read label before use.
P220: Keep/Store away from clothing/.../combustible materials.
P270: Do not eat, drink or smoke when using this product.

IUCLID data (7)


Additional labelling requirements
Special Irish labelling provisions: Use Biocides Safely and Sustainably It is illegal to use this product for uses or in a manner other than that prescrib...
Additional labelling
Special Irish labelling provisions: Use Biocides Safely and Sustainably It is illegal to use this product for uses or in a manner other than that pres
Notes
Note A
Note A
Without prejudice to Article 17(2), the name of the substance must appear on the label in the form of one of the designations given in Part 3.
In Part 3, use is sometimes made of a general description such as "... compounds" or "... salts". In this case, the supplier is required to state on the label the correct name, due account being taken of section 1.1.1.4.

Outcome in the generated SPC (7)

Additional labelling requirements (CLP supplemental hazard statement):
Special Irish labelling provisions: Use Biocides Safely and Sustainably It is illegal to use this product for uses or in a manner other than that prescribed on this label. For professional product IE/BPA 70025 only: Not For Amateur Sale

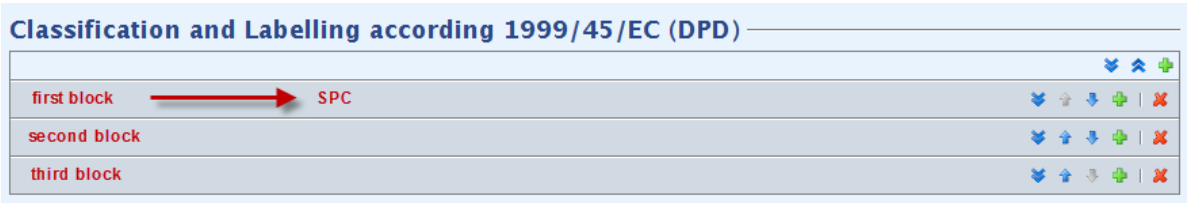
Notes:

Note A
Without prejudice to Article 17(2), the name of the substance must appear on the label in the form of one of the designations given in Part 3.
In Part 3, use is sometimes made of a general description such as "... compounds" or "... salts". In this case, the supplier is required to state on the label the correct name, due account being taken of section 1.1.1.4.

Please note that in the example above all fields were filled in. If a field in IUCLID section 12.1 is empty, then the corresponding heading is not displayed in the SPC.

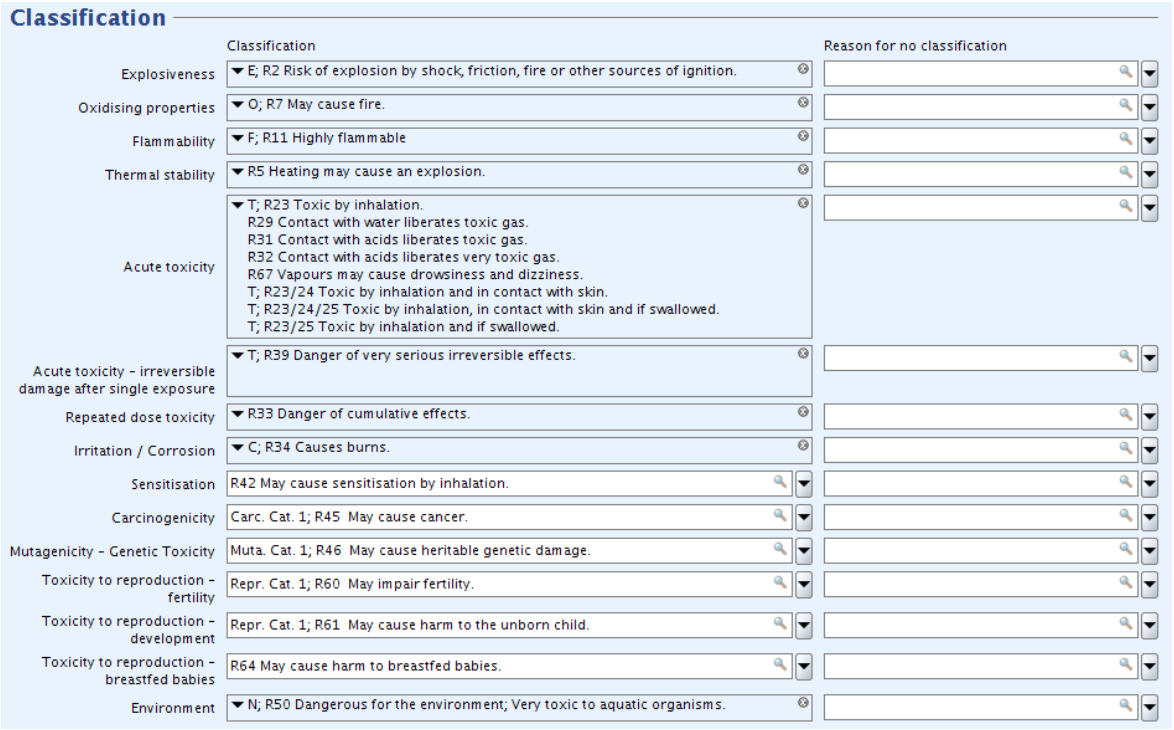
4.10 SPC SECTION 4.2

Please note that if there is more than one endpoint in section 12.2 DSD-DPD, only the first block will be transferred to SPC.



An example of the data transferred from the section 12.1 to the SPC has been divided in four smaller parts below.

IUCLID data (1)


Classification
Classification
Reason for no classification
Explosiveness
E; R2 Risk of explosion by shock, friction, fire or other sources of ignition.
Oxidising properties
O; R7 May cause fire.
Flammability
F; R11 Highly flammable
Thermal stability
R5 Heating may cause an explosion.
Acute toxicity
T; R23 Toxic by inhalation.
R29 Contact with water liberates toxic gas.
R31 Contact with acids liberates toxic gas.
R32 Contact with acids liberates very toxic gas.
R67 Vapours may cause drowsiness and dizziness.
T; R23/24 Toxic by inhalation and in contact with skin.
T; R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
T; R23/25 Toxic by inhalation and if swallowed.
Acute toxicity - irreversible damage after single exposure
T; R39 Danger of very serious irreversible effects.
Repeated dose toxicity
R33 Danger of cumulative effects.
Irritation / Corrosion
C; R34 Causes burns.
Sensitisation
R42 May cause sensitisation by inhalation.
Carcinogenicity
Carc. Cat. 1; R45 May cause cancer.
Mutagenicity - Genetic Toxicity
Muta. Cat. 1; R46 May cause heritable genetic damage.
Toxicity to reproduction - fertility
Repr. Cat. 1; R60 May impair fertility.
Toxicity to reproduction - development
Repr. Cat. 1; R61 May cause harm to the unborn child.
Toxicity to reproduction - breastfed babies
R64 May cause harm to breastfed babies.
Environment
N; R50 Dangerous for the environment; Very toxic to aquatic organisms.

Outcome in the generated SPC (1)

Table 7. Classification and labelling for physicochemical properties

Category of danger	Classification
Explosive:	E; R2 Risk of explosion by shock, friction, fire or other sources of ignition.
Oxidising:	O; R7 May cause fire.
Flammable:	F; R11 Highly flammable

Table 8. Classification and labelling for health hazards

Category of danger	Classification
Acute toxicity:	T; R23 Toxic by inhalation. R29 Contact with water liberates toxic gas. R31 Contact with acids liberates toxic gas. R32 Contact with acids liberates very toxic gas. R67 Vapours may cause drowsiness and dizziness. T; R23/24 Toxic by inhalation and in contact with skin. T; R23/24/25 Toxic by inhalation, in contact with skin and if swallowed. T; R23/25 Toxic by inhalation and if swallowed.
Acute toxicity - irreversible damage after single exposure:	T; R39 Danger of very serious irreversible effects.
Repeated dose toxicity:	R33 Danger of cumulative effects.
Corrosive / Irritant:	C; R34 Causes burns.
Sensitisation:	R42 May cause sensitisation by inhalation.
Carcinogenicity:	Carc. Cat. 1; R45 May cause cancer.
Mutagenicity - Genetic Toxicity:	Muta. Cat. 1; R46 May cause heritable genetic damage.
Toxicity to reproduction - fertility:	Repr. Cat. 1; R60 May impair fertility.
Toxicity to reproduction - development:	Repr. Cat. 1; R61 May cause harm to the unborn child.
Toxicity to reproduction - breastfed babies:	R64 May cause harm to breastfed babies.

Table 9. Classification and labelling for the environment

Category of danger	Classification
Environment:	N; R50 Dangerous for the environment; Very toxic to aquatic organisms.

IUCLID data (2)

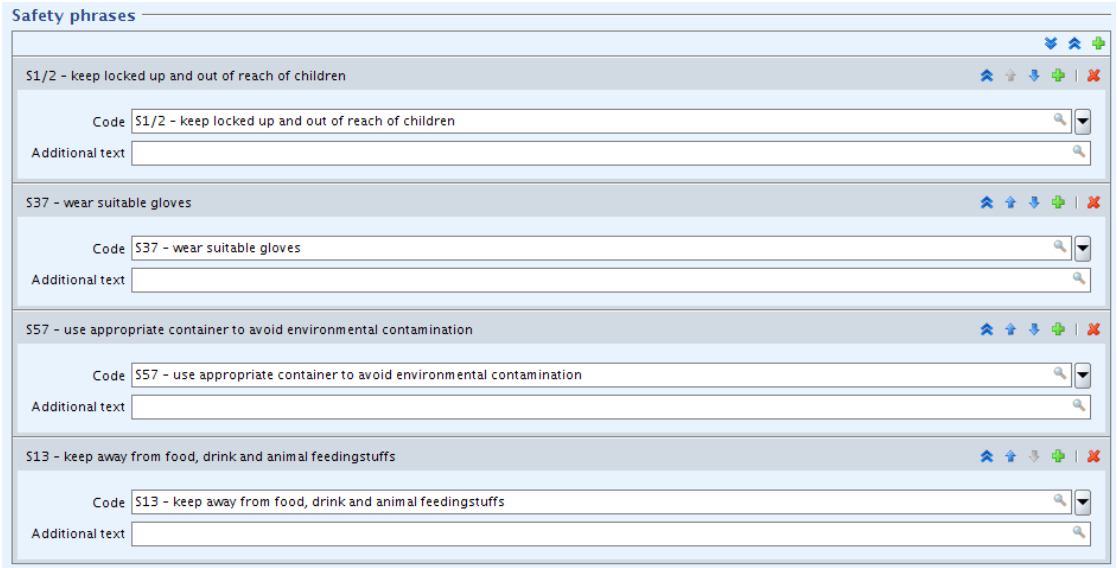
Outcome in the generated SPC (2)

Labelling

Indication of danger:
N - dangerous for the environment
T - toxic

R-phrases:
R1 - Explosive when dry

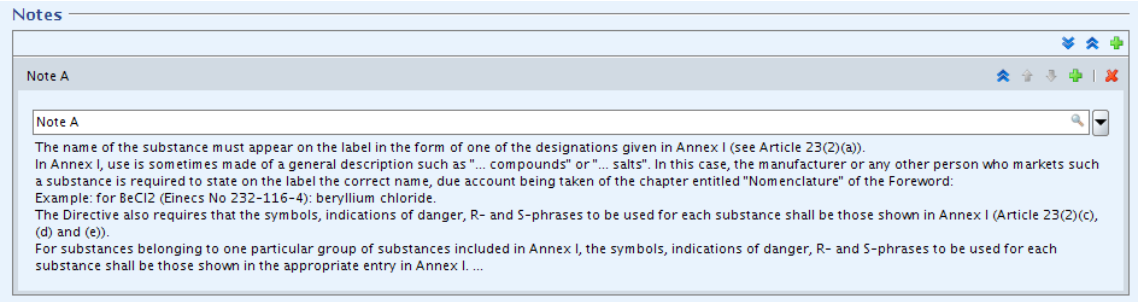
IUCLID data (3)


Safety phrases
S1/2 - keep locked up and out of reach of children
Code S1/2 - keep locked up and out of reach of children
Additional text
S37 - wear suitable gloves
Code S37 - wear suitable gloves
Additional text
S57 - use appropriate container to avoid environmental contamination
Code S57 - use appropriate container to avoid environmental contamination
Additional text
S13 - keep away from food, drink and animal feedingstuffs
Code S13 - keep away from food, drink and animal feedingstuffs
Additional text

Outcome in the generated SPC (3)

S-phrases:
S1/2 - keep locked up and out of reach of children
S37 - wear suitable gloves
S57 - use appropriate container to avoid environmental contamination
S13 - keep away from food, drink and animal feedingstuffs

IUCLID data (4)


Notes
Note A
Note A
The name of the substance must appear on the label in the form of one of the designations given in Annex I (see Article 23(2)(a)).
In Annex I, use is sometimes made of a general description such as "... compounds" or "... salts". In this case, the manufacturer or any other person who markets such a substance is required to state on the label the correct name, due account being taken of the chapter entitled "Nomenclature" of the Foreword:
Example: for BeCl2 (Einecs No 232-116-4): beryllium chloride.
The Directive also requires that the symbols, indications of danger, R- and S-phrases to be used for each substance shall be those shown in Annex I (Article 23(2)(c), (d) and (e)).
For substances belonging to one particular group of substances included in Annex I, the symbols, indications of danger, R- and S-phrases to be used for each substance shall be those shown in the appropriate entry in Annex I. ...

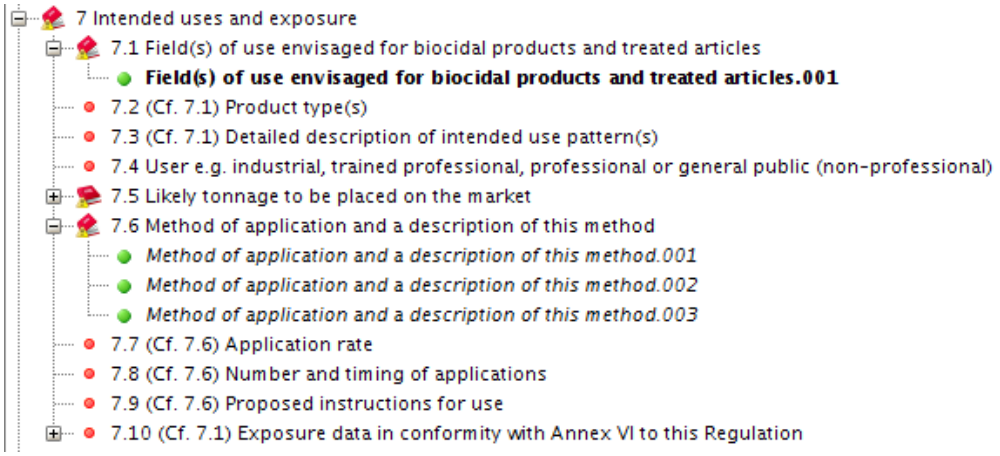
Outcome in the generated SPC (4)

Notes:

Note A
The name of the substance must appear on the label in the form of one of the designations given in Annex I (see Article 23(2) (a)).
In Annex I, use is sometimes made of a general description such as "... compounds" or "... salts". In this case, the manufacturer or any other person who markets such a substance is required to state on the label the correct name, due account being taken of the chapter entitled "Nomenclature" of the Foreword:
Example: for BeCl2 (Einecs No 232-116-4): beryllium chloride.
The Directive also requires that the symbols, indications of danger, R- and S-phrases to be used for each substance shall be those shown in Annex I (Article 23(2) (c), (d) and (e)).
For substances belonging to one particular group of substances included in Annex I, the symbols, indications of danger, R- and S-phrases to be used for each substance shall be those shown in the appropriate entry in Annex I....

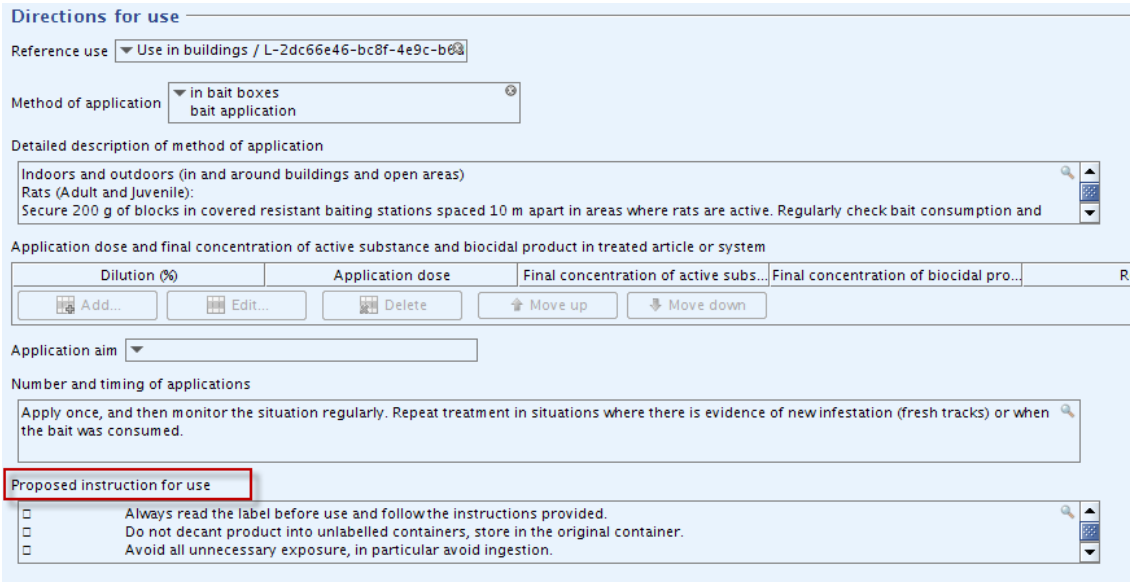
Please note that in the example above all fields were filled in. If a field in IUCLID section 12.1 is empty, then the corresponding heading is not displayed in the SPC.

4.11 SPC SECTION 5.1. INSTRUCTIONS FOR USE (IUCLID SECTION 7.6)


7 Intended uses and exposure
7.1 Field(s) of use envisaged for biocidal products and treated articles
Field(s) of use envisaged for biocidal products and treated articles.001
7.2 (Cf. 7.1) Product type(s)
7.3 (Cf. 7.1) Detailed description of intended use pattern(s)
7.4 User e.g. industrial, trained professional, professional or general public (non-professional)
7.5 Likely tonnage to be placed on the market
7.6 Method of application and a description of this method
Method of application and a description of this method.001
Method of application and a description of this method.002
Method of application and a description of this method.003
7.7 (Cf. 7.6) Application rate
7.8 (Cf. 7.6) Number and timing of applications
7.9 (Cf. 7.6) Proposed instructions for use
7.10 (Cf. 7.1) Exposure data in conformity with Annex VI to this Regulation

Note: The small dots next to some sections, e.g. 7.7 or 7.8 mean the visual link between these sections and the section mentioned between brackets (i.e. 7.6). Therefore the information related to sections marked with dots should be inserted in the section mentioned in the brackets.

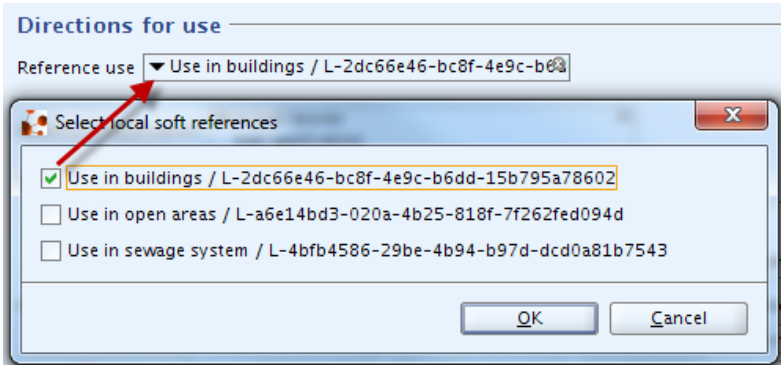
The field below marked in red has to be filled in before the generation of the instruction for use in the SPC.


Directions for use
Reference use
Use in buildings / L-2dc66e46-bc8f-4e9c-b6
Method of application
in bait boxes
bait application
Detailed description of method of application
Indoors and outdoors (in and around buildings and open areas)
Rats (Adult and Juvenile):
Secure 200 g of blocks in covered resistant baiting stations spaced 10 m apart in areas where rats are active. Regularly check bait consumption and
Application dose and final concentration of active substance and biocidal product in treated article or system
Dilution (%)
Application dose
Final concentration of active subs...
Final concentration of biocidal pro...
Add...
Edit...
Delete
Move up
Move down
Application aim
Number and timing of applications
Apply once, and then monitor the situation regularly. Repeat treatment in situations where there is evidence of new infestation (fresh tracks) or when the bait was consumed.
Proposed instruction for use
Always read the label before use and follow the instructions provided.
Do not decant product into unlabelled containers, store in the original container.
Avoid all unnecessary exposure, in particular avoid ingestion.

The above field should contain the necessary instructions for use. For example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

The instruction for use is to be prepared separately for each use described in section 7.1.

In each endpoint of section 7.6 there is an indication to which use this very specific endpoint relates:



If the whole content of section 7.6 is the same for more than one use, then the endpoint can be linked to all relevant uses.

The instructions for use displayed in the SPC are named using the rlevant use number(s) and use name(s).

Outcome in the generated SPC

5. Directions for use

NOTE: All elements in the section 5 would need to appear on the labelling

5.1. Instructions for use

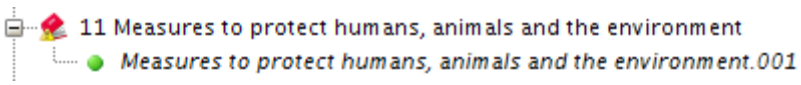
Use # 1 - Use in buildings

- Always read the label before use and follow the instructions provided.
- Do not decant product into unlabelled containers, store in the original container.
- Avoid all unnecessary exposure, in particular avoid ingestion.
- Do not apply to areas where food/feed, food utensils or food processing surfaces may come into contact with, or be contaminated by the product
- This product shall not be used as a tracking poison
- A thorough survey of the infested area is essential, particularly in secluded and sheltered places, to determine the extent of the infestation.
- Baits must be secured inside tamper resistant bait boxes or other secure coverings to minimize the risk of consumption and poisoning to children, companion animals and other non-target animals.
- Bait boxes must be secured and placed in areas inaccessible to children, pets and non-target animals.
- For professional use, where applying in public areas, the areas being treated must be clearly signed that rodenticide control is in operation. Signage must provide information on the risks of interfering with the product and dead rodents, as well as indicating first aid measures.
- For professional users the use of appropriate personal protective equipment (PPE) is advised. The use of gloves is advised for hand protection. Apply in a well ventilated area
- Dead rodent bodies, remains of unused bait or any fragments of bait found away from the bait station must be collected during all control operations to minimize the risk of consumption and poisoning to children, companion animals and other non-target animals.
- Wash hands and face after application and use of the product, and before eating, drinking or smoking.

Use # 2 - Use in open areas

- Always read the label before use and follow the instructions provided.
- Do not decant product into unlabelled containers, store in the original container.
- Avoid all unnecessary exposure, in particular avoid ingestion.
- Do not apply to areas where food/feed, food utensils or food processing surfaces may come into contact with, or be contaminated by the product

4.12 SPC SECTION 5.2. PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT (IUCLID SECTION 11)



IUCLID data (part of the IUCLID section 11)

Particulars of likely direct or indirect adverse effects

The active substance in the form of baits may be palatable to humans and non-target species in sufficient quantity to produce toxic effects.

Effects result from the inhibition of blood coagulation as coumarin interacts with vitamin K1. Poisoning symptoms may include: bruising easily, nose

First aid instructions, antidotes

General note:	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
Oral:	In case of ingestion or if swallowed seek medical advice immediately.
Eyes:	In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with water for 15-20 minutes. Seek m

Emergency measures to protect environment in case of accident

The product contains an aversive agent (Licool) to prevent ingestion.
The product contains a coloured dye to prevent consumption by non-target organisms, specifically birds.
Avoid release to the environment. Refer to special instructions/Safety data sheet.

Outcome in the generated SPC

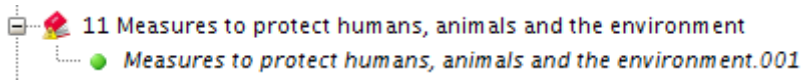
5.2. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Particulars of likely direct or indirect effects: The active substance in the form of baits may be palatable to humans and non-target species in sufficient quantity to produce toxic effects.
Effects result from the inhibition of blood coagulation as coumarin interacts with vitamin K1. Poisoning symptoms may include: bruising easily, nose or gum bleeds, blood in stools or urine, excessive bleeding from minor cuts or abrasions. Note that poisoning symptoms may develop over the course of several days.

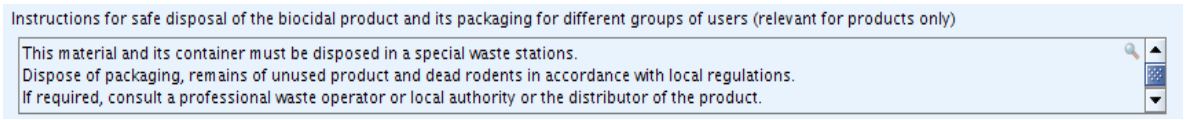
First aid instructions: General note: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
Oral: In case of ingestion or if swallowed seek medical advice immediately.
Eyes: In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with water for 15-20 minutes. Seek medical advice immediately.
Note to Physician:
Coumarin is an indirect anti-coagulant. Phytomenadione, Vitamin K1, is antidotal. Determine prothrombin times not less than 18 hours after consumption. If elevated, administer Vitamin K1 until prothrombin time normalises. Continue determination of prothrombin time for two weeks after withdrawal of antidote and resume treatment if elevation occurs in that time.
POISON INFORMATION
For information or to report a poisoning incident contact The National Poisons Information Centre, Helsinki Hospital, Helsinki (11111111111111111), retain the label for reference.
The product contains an aversive agent (Licool) to prevent ingestion.
The product contains a coloured dye to prevent consumption by non-target organisms, specifically birds.
Dermal: The use of gloves is advised for hand protection.
In case of contact with skin, wash with soap and water. Remove and launder any contaminated clothing.

Emergency measures to protect the environment: The product contains an aversive agent (Licool) to prevent ingestion.
The product contains a coloured dye to prevent consumption by non-target organisms, specifically birds.
Avoid release to the environment. Refer to special instructions/Safety data sheet.

4.13 SPC SECTION 5.3. INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING (IUCLID SECTION 11)



IUCLID data (part of the IUCLID section 11)

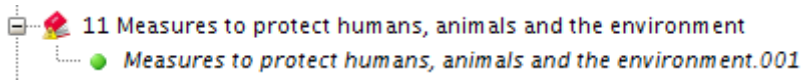

Instructions for safe disposal of the biocidal product and its packaging for different groups of users (relevant for products only)
This material and its container must be disposed in a special waste stations.
Dispose of packaging, remains of unused product and dead rodents in accordance with local regulations.
If required, consult a professional waste operator or local authority or the distributor of the product.

Outcome in the generated SPC

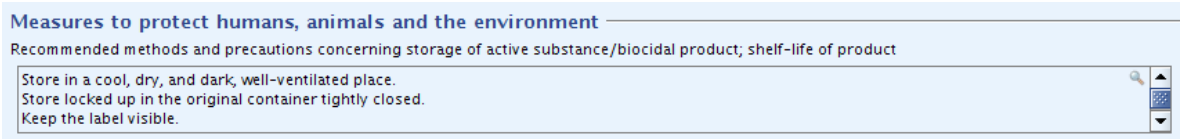
5.3. Instructions for safe disposal of the product and its packaging

This material and its container must be disposed in a special waste stations.
Dispose of packaging, remains of unused product and dead rodents in accordance with local regulations.
If required, consult a professional waste operator or local authority or the distributor of the product.

4.14 SPC SECTION 5.4. CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE (IUCLID SECTION 11)



IUCLID data (part of the IUCLID section 11)


Measures to protect humans, animals and the environment
Recommended methods and precautions concerning storage of active substance/biocidal product; shelf-life of product
Store in a cool, dry, and dark, well-ventilated place.
Store locked up in the original container tightly closed.
Keep the label visible.

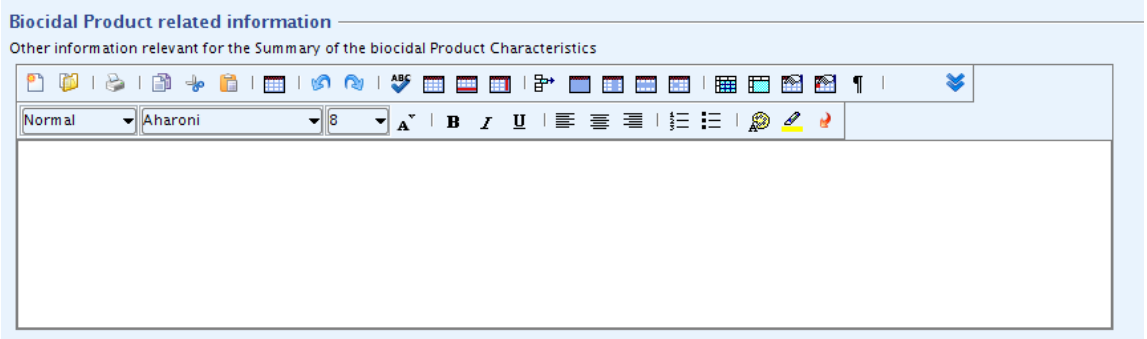
Outcome in the generated SPC

5.4. Conditions of storage and shelf-life of the product under normal conditions of storage

Store in a cool, dry, and dark, well-ventilated place.
Store locked up in the original container tightly closed.
Keep the label visible.
The shelf-life of the product is considered stable for two years at ambient temperatures.
Use by the expiry date shown on the pack.

4.15 SPC SECTION 6. OTHER INFORMATION (IUCLID SECTION 13)

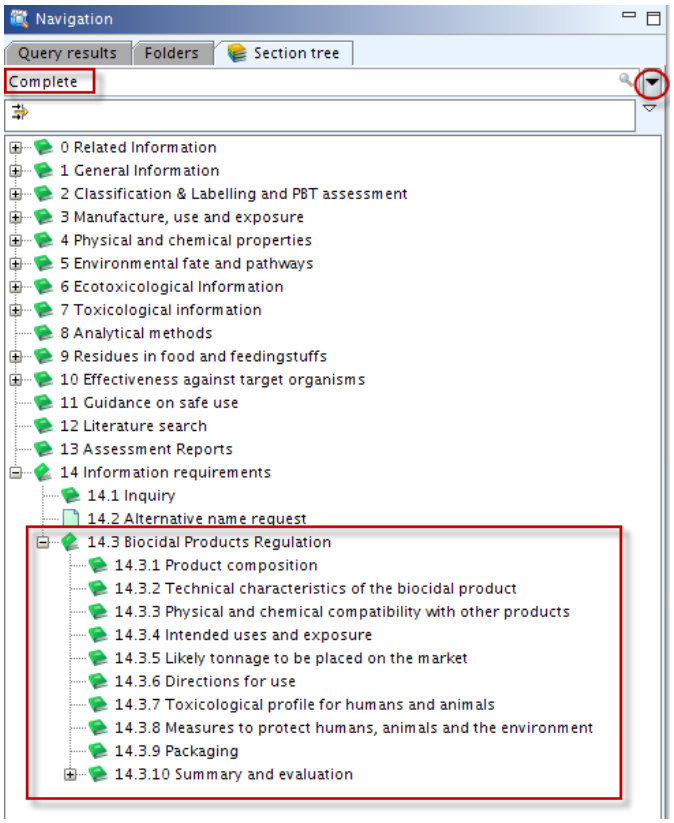
In IUCLID section 13, a field is available in which the user can insert any other information important for the SPC. Tables can be included.



PART II: SPECIFICATIONS OF THE SPC TEMPLATE

In the specifications below, the IUCLID section numbering has been used whereas in the first part of this manual, the numbering of the sections in the IUCLID view for 'BPR Biocidal product authorisation' was used.

To see the numbering used in specification, the 'Complete' view has to be selected in IUCLID.


Navigation
Query results
Folders
Section tree
Complete
0 Related Information
1 General Information
2 Classification & Labelling and PBT assessment
3 Manufacture, use and exposure
4 Physical and chemical properties
5 Environmental fate and pathways
6 Ecotoxicological Information
7 Toxicological information
8 Analytical methods
9 Residues in food and feedingstuffs
10 Effectiveness against target organisms
11 Guidance on safe use
12 Literature search
13 Assessment Reports
14 Information requirements
14.1 Inquiry
14.2 Alternative name request
14.3 Biocidal Products Regulation
14.3.1 Product composition
14.3.2 Technical characteristics of the biocidal product
14.3.3 Physical and chemical compatibility with other products
14.3.4 Intended uses and exposure
14.3.5 Likely tonnage to be placed on the market
14.3.6 Directions for use
14.3.7 Toxicological profile for humans and animals
14.3.8 Measures to protect humans, animals and the environment
14.3.9 Packaging
14.3.10 Summary and evaluation

SPECIFICATIONS OF THE SUMMARY OF PRODUCT CHARACTERISTICS TEMPLATE

This document provides specifications of the Summary of Product Characteristics (SPC) template for biocidal product.

This template will allow the applicant to generate a draft SPC from the information stored in IUCLID. The document should be editable. Printing and saving in xml and rtf format will be possible in the same way as for the CSR generated by the CSR plug-in.

The IUCLID sections numbering used in the document follows the 'Complete' template. The only exception to this rule is the 'NOTE text' for the applicant, in section 3, Authorised use(s), where the 'BPR Biocidal product authorisation' template numbering is used; however these are just information that should be printed for the user and are not describing a rule to extract data from IUCLID into the SPC.

The xpaths for the relevant fields from the flexible parts are listed in a separate document: *xpaths.doc*.

CONVENTIONS

The following conventions are used:

- Placeholders for IUCLID 5.5 source fields are set between less than / greater than signs, i.e., <placeholder>. Example: <Trade name>.
- Annotations (additional information useful for the specifications but not to be inserted in the generated report) are set between brackets and formatted in italics. Example: *[IUCLID source: section 1.1 Identification], [This information should be retrieved from linked Legal entity (Sites)]*
- The content between *>>>NOTE:* and *<<<* should be displayed to the applicant according to the specified rule, but should not be considered as a part of the SPC (i.e. it is expected that the user will remove these notes while further editing the draft SPC automatically generated).
- Whenever the option 'other:' is chosen, the word 'other' should not be displayed, only the content of the additional text field, e.g. If material of packaging is defined as 'other: plastic PP, PE, PCV, PS', only 'plastic PP, PE, PCV, PS' should be displayed in the SPC.

1 Administrative information

1.1 Trade name of the product

[IUCLID source: section 1.1 Identification]

Trade name	**Country (if relevant)**
<Trade name> *[In case the product would have more than one trade name specified in the table 'Other names', all trade names should be retrieved in separate rows]*	<Country> *[If for one of the 'Trade name' items, the field 'Country' is filled, the content should be retrieved in the relevant row]*

1.2 Authorisation holder

[This section will contain information that are not stored in IUCLID and will be added in a later stage of the authorisation process (these data will be stored in R4BP 3). Therefore these fields should be kept empty when the draft SPC is generated (as text fields).]

>>>NOTE: Please insert the following information related to the authorisation manually once available<<< *[Rule: Always printed]*

Name and address of the authorisation holder	Name	
	Address	>>>NOTE: *Address:* *Postal code:* *Town:* *Region/State:* *Country:* *Fax:* *E-mail:* *Web site:<<<* *[Rule: Always printed]*
Authorisation number >>>NOTE: in the case of a product belonging to a biocidal product family, the authorisation number should be that of the biocidal product family and a suffix added for that individual product)<<<		
Date of the authorisation		
Expiry date of the authorisation		

1.3 Manufacturer(s) of the product

[IUCLID source: mixture/product dataset, section 1.7 Suppliers]

Name of manufacturer	<Legal entity name>
Address of manufacturer	Address 1: <Address> Address 2: <Address> Postal code: <Postal code> Town: <Town> Region/State: <Region/State> Country: <Country> Fax: <Fax> E-mail: <E-mail> Web site: <Web site> *[This information should be retrieved from the linked Legal entity (Contact address)]*
Location of manufacturing sites	Address 1: <Address> Address 2: <Address> Postal code: <Postal code> Town: <Town> Region/State: <Region/State> Country: <Country> Fax: <Fax> E-mail: <E-mail> Web site: <Web site> *[This information should be retrieved from the linked Legal entity (Contact persons identified with Contact type = 'other: site))]*
	[For each plant location a separate row should be added]

[For each manufacturer listed in each block in section 1.7 a separate table should be provided]

1.4 Manufacturer(s) of the active substance(s)

[IUCLID source: substance dataset, section 1.7 Suppliers if not stated otherwise in the table below]

Active substance	<Public name> *[Public name should be retrieved from section 1.1 of the substance referred in section 14.3.1 (Product composition), of the product dataset, as Active Substance – option Active Substance selected in the field Function]*
Name of manufacturer	<Legal entity name> [Using the same logic as above, section 1.7 of the active substance dataset, linked Legal entity]
Address of manufacturer	Address 1: <Address> Address 2: <Address> Postal code: <Postal code> Town: <Town> Region/State: <Region/State> Country: <Country> Fax: <Fax> E-mail: <E-mail> Web site: <Web site> *[This information should be retrieved from the linked Legal entity in section 1.7 (Contact information, Contact address), for the relevant active substance]*
Location of manufacturing sites	Address 1: <Address> Address 2: <Address> Postal code: <Postal code> Town: <Town> Region/State: <Region/State> Country: <Country> Fax: <Fax> E-mail: <E-mail> Web site: <Web site> *[This information should be retrieved from the linked Legal entity in section 1.7 (Contact information, Contact persons identified with the Contact type 'other: site'), for the relevant active substance]*
	[For each plant location a separate row should be added]

[For each manufacturer, specified in section 1.7 of each active substance referred in section 14.3.1 a separate table should be provided]

2 Product composition and formulation

2.1 Qualitative and quantitative information on the composition of the product

[IUCLID source for columns 1-2 and 4-5: section 1.1 of the substance of mixture dataset, identified as product components in the Biocidal product dataset flagged either as active substance or

substance of concern, section 14.3.1, and in the linked reference substance in the same section of the substance dataset]

[IUCLID source for column 3 and 6: section 14.3.1 Product composition: endpoint study record]

Common name *[1]*	**IUPAC name *[2]***	**Function *[3]***	**CAS number *[4]***	**EC number *[5]***	**Content (%) *[6]***
<Chemical name or Mixture/Product name> *[From section 1.1 of the product component]*	<IUPAC name> *[Only for substance dataset, from the reference substance linked to section 1.1]*	<Function> *See below*	<CAS number> *[Only for substance dataset, from the reference substance linked to section 1.1]*	<EC number> *[Only for substance dataset, from the reference substance linked to section 1.1]*	<Concentration %>

[Separate rows should be added for all product components identified as active substance or substance of concern listed in section 14.3.1 of the product dataset.]

2.2 Type of formulation

[IUCLID source: section 14.3.1 Product composition: endpoint study record]

<Formulation type>

[As formulation type is a pick list with multiple selections allowed, there would be many items to be listed. They could be separated by a coma, i.e.:

OD Oil dispersion, OL Oil miscible liquid, unspecified oil]

3. Authorised use(s)

[IUCLID source: Product dataset, section 14.3.4 Intended uses and exposure, 14.3.6 Directions for use, 10.1 Effectiveness against target organisms and intended uses – general information, 14.3.9 Packaging]

[Whenever there is more than one endpoint study record in the section 14.3.4 Intended uses and exposure or more than one row in the table 'Use(s) pattern', the table below should be repeated.

The following items, belonging to section 14.3.4 will be retrieved for each use in each endpoint:

- *Product type (the same for all uses in one endpoint)*
- *The same 'description of the authorised use' should be repeated, per use in the same endpoint study record*
- *Field(s) of use*
- *Category(ies) of users*

The following items, belonging to section 14.3.6, will also be retrieved according to the link between section 14.3.6 and 14.3.4 (reference use):

- *Application method(s)*
- *Application rate(s) and frequency*

For the following items, the content will be the same for each table:

- *Target organism (including development stage), from section 10.1*
- *Pack sizes and packaging material, from section 14.3.9]*

Table <x>: Use # <Use number> - <Use Name>

[Each table should have a title created in the following way: Table x (where x – successive number): <Use number><Use Name>]

Product Type	**<Product type>***[from section 14.3.4* *As Product type is a pick list with multiple selections allowed, there would be many items to be listed. They could be listed, one per line, e.g.:* *EU BPR Product type 1: Human hygiene (Disinfectants)* *EU BPR Product type 3: Veterinary hygiene (Disinfectants)* *…]*
Where relevant, an exact description of the authorised use	*<Detailed description of uses including in treated articles>* *[From section 14.3.4]*
Target organism (including development stage)	Scientific name: <Scientific name>, common name: <Common name>, development stage: <Developm. stage> *[Group of fields to be repeated for each repeatable block 'Target organisms', under the label 'Pest / target organisms to be controlled, from section 10.1 of the product dataset]*
Field of use	<Field of use> [From section 14.3.4. Several values are possible: list of values in

	all fi]
Application method(s)	**Method of application:** <Method of application> **Detailed description of the method:** <Detailed description of method of application>
Application rate(s) and frequency	<Application dose, qualifier> <Application dose, value> <Application dose, qualifier> <Application dose, value> <Application dose, unit> <Number and timing of application> *[The content of more than one field would be retrieved in here. Also, the applicant is allowed to provide several option of application rate, depending on dilution. Therefore there is a need to provide additional phrases, and use as well a dilution value. It could be:* **The application rate is** <Application dose, qualifier> <Application dose, value> <Application dose, qualifier> <Application dose, value> <Application dose, unit> **for the dilution** <Dilution (%)> **%. Number and timing of application:** <Number and timing of application> *The sentence 'The application rate is… %' would be repeated for each row in the IUCLID table.* *For the dilution value 100 or whenever the field* <Dilution (%)> *is left empty, the phrase 'for the dilution* <Dilution (%)> *%' would not be displayed.* *In case when the table 'Application dose and final concentration of active substance and biocidal product in treated article or system' is empty, the sentence 'The application rate is … for the dilution … %.' Will not be displayed.* *Number and timing of application described in one field, for all dilutions, therefore the content of this field should be retrieved only once.]*
Category(ies) of users	<User>
Pack sizes and packaging material	<Size of packaging in contact with the product (container size), qualifier> <Size of packaging in contact with the product (container size), value> <Size of packaging in contact with the product (container size), qualifier> <Size of packaging in contact with the product (container size), value> <Size of packaging in contact with the product (container size), unit> <Material of packaging in contact with the product (container material)><Further description of the packaging in contact with the product> *[The content of more than one field would be retrieved in here. Therefore there is a need to provide additional phrases. It could be:* **Pack size is:** <Size of packaging in contact with the product (container size), qualifier> <Size of packaging in contact with the product (container size), value> <Size of packaging in contact with the product (container size), qualifier> <Size of packaging in contact with the product (container size), value> <Size of packaging in contact with the product (container size), unit>**, and the packaging material is** <Material of packaging in contact with the product (container material)> **Further description of the**

	packaging: <Further description of the packaging in contact with the product> **Safety features:** <Safety features of the packaging>*]*

>>>NOTE: In case that there is more than one row in the table 'Use(s) pattern' or more than one endpoint in section 7.1 Field(s) of uses envisaged for biocidal products and treated articles, the following items have been retrieved for each use in each endpoint to the relevant table (one table – one use):

- Product type (the same for all uses in one endpoint)
- Where relevant, an exact description of the authorised use (the same description for all uses in one endpoint, might be adapted manually to each use if needed)
- Field of use
- Category(ies) of users

The following items, belonging to section 7.6 Method of application and a description of this method, have been retrieved accordingly to the link between section 7.6 and 7.1 (reference use) to the relevant table (one table – one use):

- Application method(s)
- Application rate(s) and frequency

For the following items, the content provided to all tables (for all endpoints) will be the same. Therefore, please ensure that the content specific to each use is inserted to the relevant table, by adapting it manually:

- Target organism (including development stage)
- Pack sizes and packaging material]

<<< *[Rule: Printed whenever there is more than one row in the table 'Use(s) pattern' or more than one endpoint study record in the section 14.3.4 Intended uses and exposure]*

4 Hazard and precautionary statements

4.1 Classification and labelling of the product according to the Regulation (EC) 1272/2008

[IUCLID source: section 2.1 GHS]

No relevant information available *[Rule: Print if none of the fields specified below is populated and the checkbox "not classified" is not ticked. Note: This default text is not printed if any field "Reason for no classification" is populated with the IUCLID default phrase "data lacking".]*

Classification:

The biocidal product is not classified *[Rule: Print if the checkbox "not classified" is selected.]*

The biocidal product is classified as follows: *[Rule: Print if either of the "Classification" fields is populated. Rule 2: This also triggers the output of the following table(s). Rule 3: Print each item (row) if any of the fields ("Hazard category", "Hazard statement) is populated.]*

Table 1. Classification and labelling according to CLP/GHS for physicochemical properties

Hazard class	**Hazard category**	**Hazard statement**
Explosives:	<category>	<hazardStatement>
Flammable gases and chemically unstable gases:	<category>	<hazardStatement>
Aerosols:	<category>	<hazardStatement>
Oxidising gases:	<category>	<hazardStatement>
Gases under pressure:	<category>	<hazardStatement>
Flammable liquids:	<category>	<hazardStatement>
Flammable solids:	<category>	<hazardStatement>
Self-reactive substances and mixtures:	<category>	<hazardStatement>
Pyrophoric liquids:	<category>	<hazardStatement>
Pyrophoric solids:	<category>	<hazardStatement>
Self-heating substances and	<category>	<hazardStatement>

Hazard class	**Hazard category**	**Hazard statement**
mixtures:		
Substances and mixtures which in contact with water emit flammable gases:	<category>	<hazardStatement>
Oxidising liquids:	<category>	<hazardStatement>
Oxidising solids:	<category>	<hazardStatement>
Organic peroxides:	<category>	<hazardStatement>
Corrosive to metals:	<category>	<hazardStatement>

Table 2. Classification and labelling according to CLP/GHS for health hazards

Hazard class	**Hazard category**	**Hazard statement**
Acute toxicity - oral:	<category>	<hazardStatement>
Acute toxicity - dermal:	<category>	<hazardStatement>
Acute toxicity - inhalation:	<category>	<hazardStatement>
Skin corrosion / irritation:	<category>	<hazardStatement>
Serious damage / eye irritation:	<category>	<hazardStatement>
Respiratory sensitisation:	<category>	<hazardStatement>
Skin sensitisation:	<category>	<hazardStatement>
Aspiration hazard:	<category>	<hazardStatement>
Reproductive Toxicity:	<category> Specific effect: <Specific effect> Route of exposure: <Route	<hazardStatement>

Hazard class	**Hazard category**	**Hazard statement**
	of exposure>	
Reproductive Toxicity. Effects on or via lactation:	<category>	<hazardStatement>
Germ cell mutagenicity:	<category> Route of exposure: <Route of exposure>	<hazardStatement>
Carcinogenicity:	<category> Route of exposure: <Route of exposure>	<hazardStatement>
Specific target organ toxicity – single exposure:	<category> Affected organs: <Affected organs> Route of exposure: <Route of exposure>	<hazardStatement>
Specific target organ toxicity – repeated exposure:	<category> Affected organs: <Affected organs> Route of exposure: <Route of exposure>	<hazardStatement>

Table 3. Classification and labelling according to CLP/GHS for the environment

Hazard class	**Hazard category**	**Hazard statement**
Hazards to the aquatic environment (acute/short-term):	<category>	<hazardStatement>
Hazards to the aquatic environment (chronic/long-term):	<category>	<hazardStatement>
Hazardous to the ozone layer:	<category>	<hazardStatement>

Table 4. Classification and labelling according to CLP/GHS for additional hazard classes

Additional hazard classes:	<Additional hazard classes>
Additional hazard statements:	<Additional hazard statements>

Labelling:

Signal word: <Signal word>

Hazard pictogram: <Hazard pictogram>

Hazard statements: <Hazard statement> (<Additional text>)

Precautionary statements: <Precautionary statement> (<Additional text>)

Additional labelling requirements (CLP supplemental hazard statement):

<CLP supplemental hazard statement> (Additional text: <Additional text>)

[No heading] <Additional labelling>

Notes:

<Notes>

>>>NOTE: For micro-organisms based products: indication of the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). <<< *[Rule: Always printed]*

4.2 Classification and labelling of the product according to the criteria in Directive 67/548/EEC (DSD) and Directive 1999/45/EC (DPD)

[IUCLID source: section 2.2 DSD - DPD]

No relevant information available *[Rule: Print if none of the fields specified below is populated and the checkbox "not classified" is not ticked. Note: This default text is not printed if any field "Reason for no classification" is populated with the IUCLID default phrase "data lacking".]*

Classification

The biocidal product is not classified *[Rule: Print if the checkbox "not classified" is selected.]*

The biocidal product is classified as follows: *[Rule: Print if either of the "Classification" fields is populated.]*

Table 5. Classification and labelling for physicochemical properties

Category of danger	**Classification**
Explosive:	<Explosiveness>
Oxidising:	<Oxidising properties>
Flammable:	<Flammability>

Table 6. Classification and labelling for health hazards

Category of danger	**Classification**
Acute toxicity:	<Acute toxicity>
Acute toxicity - irreversible damage after single exposure:	<Acute toxicity - irreversible damage after single exposure>
Repeated dose toxicity:	<Repeated dose toxicity>
Corrosive / Irritant:	<Irritation / Corrosion>
Sensitisation:	<Sensitisation>
Carcinogenicity:	<Carcinogenicity>
Mutagenicity - Genetic Toxicity:	<Mutagenicity - Genetic Toxicity>
Toxicity to reproduction - fertility:	<Toxicity to reproduction - fertility>
Toxicity to reproduction - development:	<Toxicity to reproduction - development>

Category of danger	Classification
Toxicity to reproduction - breastfed babies:	<Toxicity to reproduction - breastfed babies>

Table 7. Classification and labelling for the environment

Category of danger	Classification
Environment:	<Environment>

Labelling

Symbol

Indication of danger: <Indication of danger>

R-phrases: <Risk phrases>

S-phrases: <Code> (<Additional text>)

Notes:

<Notes>

>>>NOTE: For micro-organisms based products: indication of the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). <<< *[Rule: Always printed]*

5 Directions for use

>>>NOTE: All elements in the section 5 would need to appear on the labelling<<< *[Rule: Always printed]*

5.1 Instructions for use

[IUCLID source: section 14.3.6 Directions for use]

<Proposed instruction for use> *[There could be several items to be retrieved here, as there should be specific directions for use for each document in section 14.3.4]*

>>>NOTE: Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. <<< *[Rule: Always printed]*

5.2 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

[IUCLID source: section 14.3.8 Measures to protect humans, animals and the environment]

< Particulars of likely direct or indirect adverse effects> < First aid instructions, antidotes> < Emergency measures to protect environment in case of accident> *[The content of more than one field would be retrieved in here. Therefore it would be justifiable to keep internal headings:* **Particulars of likely direct or indirect effects:** < Particulars of likely direct or indirect adverse effects> **First aid instructions:** < First aid instructions, antidotes> **Emergency measures to protect the environment:** < Emergency measures to protect environment in case of accident>*]*

5.3 Instructions for safe disposal of the product and its packaging

[IUCLID source: section 14.3.8 Measures to protect humans, animals and the environment]

<Instructions for safe disposal of the biocidal product and its packaging for different groups of users (relevant for products only)>

5.4 Conditions of storage and shelf-life of the product under normal conditions of storage

[IUCLID source: section 14.3.8 Measures to protect humans, animals and the environment]

< Recommended methods and precautions concerning storage of active substance/biocidal product; shelf-life of product>

6 Other information

[IUCLID source: section 14.3.10 Summary and evaluation]

<Other information relevant for the Summary of the biocidal Product Characteristics>

European Chemicals Agency

IUCLID 5 Guidance and Support

Report Generator – SPC generation

User Manual
July 2013 version 1.0

http://iuclid.eu